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Jewel[®] **AF**

Arrhythmia Management Device

System Reference Guide

9958E Software

**Jewel[®] AF Model 7250
Arrhythmia
Management Device**

**CAUTION: INVESTIGATIONAL DEVICE.
LIMITED BY UNITED STATES LAW TO
INVESTIGATIONAL USE.**

Investigational Device

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7250 System Reference Guide

Caution:
Exclusively for clinical investigation
(European Directive 90/385/EEC).

Caution:
Investigational Device. Limited by
United States law to investigational use.

9958E Software

Jewel[®] AF
Model 7250
Arrhythmia
Management Device

Created by Cardiovascular Technical Communications

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Introduction

Before implanting the arrhythmia management device, it is strongly recommended that the physician do the following:

- Thoroughly read this manual, the technical manuals for the leads used with the device.
- Provide a copy of the patient manual to the patient and discuss it with him or her and any other interested parties.

Medtronic requires physicians to attend an education seminar on the complete arrhythmia management device system. This includes the following topics:

- Indications for use
- Overview of the arrhythmia management device system functions
- Implant procedure
- Patient management

Automatic defibrillation was invented and patented in 1953 by Dr. F. Zacouto, who designed an external device that delivered a defibrillation impulse to the heart upon detection of very rapid ECG activity in combination with the absence of arterial pulsations.

Certain antitachycardia pacing modes of this device, invented by Dr. Fred Zacouto of Paris, France, fall under one or more patent claims of U.S. Patents 3,857,399 and 4,052,991 and corresponding patents in other countries, which are licensed exclusively to Medtronic, Inc.

The primary reference for background information is Zacouto FI, Guize LJ. Fundamentals of Orthorhythmic Pacing. In: Luderitz B, ed. Cardiac Pacing Diagnostic and Therapeutic Tools. New York: Springer-Verlag; 1976: 212-218.

See these additional references for more background information:

1. Effert S. Automatische Überwachungsgeräte und Indikation zur Implantation von elektrischen Schrittmachern. *Thoraxchirurgie und Vaskuläre Chirurgie*. 1963; 11: 158-165. This describes the automatic defibrillation equipment of Dr. F. Zacouto.
2. Guize L, Zacouto F, et al. Stimulation endocardiaques orthorhythmiques. *La Nouvelle Presse medicale*. 1974; 3(33): 2083-2086.
3. Theisen K, Zacouto F, et al. Refr ktarzeitmessung bei absoluter Arrhythmie mit orthorhythmischer Serienstimulation. *Klin. Wschr.* 1974; 52: 1082-1084.

Abbreviations and Acronyms

A-	Atrial
AF	Atrial Fibrillation
AFDI	Atrial Fibrillation Detection Interval
AMD	Arrhythmia Management Device
ARP	Atrial Refractory Period
ARS	Atrial Rate Stabilization
AT	Atrial Tachycardia (including atrial flutter)
ATDI	Atrial Tachycardia Detection Interval
ATP	Antitachycardia Pacing
AVNRT	AV Nodal Reentry Tachycardia
BOL	Beginning of Life
bpm	beats per minute
CNID	Combined (VT and VF) Number of Intervals to Detect
CV	Cardioversion
DF / Defib	Defibrillation
ECG	Electrocardiogram
EGM	Electrogram
EOL	End of Life
EPS	Electrophysiologic Study
ERI	Elective Replacement Indicator
J	joules
ms	milliseconds
mV	millivolts
NID	Number of Intervals to Detect
PAC	Premature Atrial Contraction
PAV	Paced A-V Delay
PES	Premature Electrical Stimulation
POR	Power On Reset
PP	P-P interval; an atrial interval
ppm	paces per minute

Abbreviations and Acronyms

PR	P-R interval; an interval between a P-wave and the subsequent R-wave
PVARP	Post Ventricular Atrial Refractory Period
PVC	Premature Ventricular Contraction
RCNID	Combined (VT and VF) Number of Intervals to Redetect
RNID	Number of Intervals to Redetect
RP	R-P interval; an interval between an R-wave and the subsequent P-wave
RR	R-R interval; a ventricular interval
SAV	Sensed A-V Delay
SVT	Supraventricular Tachycardia
V	volts
V-	Ventricular
VF	Ventricular Fibrillation
VFDI	Ventricular Fibrillation Detection Interval
VF NID	VF Number of Intervals to Detect
VF RNID	VF Number of Intervals to Redetect
VRP	Ventricular Refractory Period
VT	Ventricular Tachycardia
VTDI	Ventricular Tachycardia Detection Interval
VT NID	VT Number of Intervals to Detect
VT RNID	VT Number of Intervals to Redetect

Prescribing the AMD

1

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Device Description

The Medtronic® Model 7250 Jewel® AF Arrhythmia Management Device (AMD) is a multiprogrammable implantable medical device that detects and treats atrial tachycardia (AT) including atrial flutter, atrial fibrillation (AF), ventricular tachycardia (VT), ventricular fibrillation (VF), and bradycardia. When an arrhythmia is detected, the AMD delivers antitachycardia pacing, cardioversion, defibrillation, or bradycardia pacing therapy, as appropriate. By means of a hand-held telemetry device, the patient can also request the AMD to initiate atrial defibrillation therapy.

The AMD's operations are enabled and tailored to the patient's needs with an appropriate Medtronic programmer, Model 9790 series, using Medtronic application software, Model 9958E.

The AMD requires an appropriate two- or three-lead system, consisting of the following:

- atrial pacing/sensing electrodes,
- ventricular pacing/sensing electrodes,
- supraventricular high voltage electrode(s),
- ventricular high voltage electrode.

Table 1-1. Possible Lead Configurations

2 lead systems	<ul style="list-style-type: none"> • A-Pace/Sense/SVC H.V. • V-Pace/Sense/RV H.V. <p>(7250G)</p>	<ul style="list-style-type: none"> • A-Pace/Sense • V-Pace/Sense/RV and SVC H.V. <p>(7250G)</p>	
3 lead systems	<ul style="list-style-type: none"> • A-Pace/Sense • V-Pace/Sense/RV H.V. • SVC or CS H.V. <p>(7250G)</p>	<ul style="list-style-type: none"> • A-Pace/Sense • V-Pace/Sense/RV and SVC H.V. • CS H.V. <p>(7250H)</p>	<ul style="list-style-type: none"> • A-Pace/Sense/SVC H.V. • V-Pace/Sense/RV H.V. • CS H.V. <p>(7250H)</p>

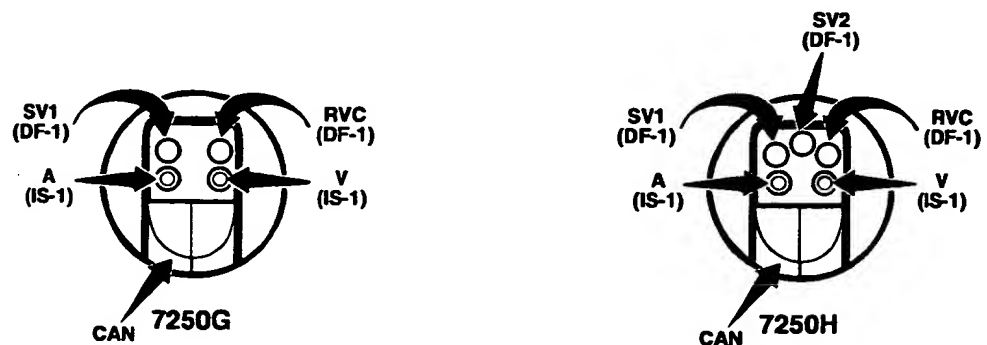


Figure 1-1. Lead Connections

Indications

The AMD is intended for use in patients who are at high risk of sudden death due to ventricular tachyarrhythmias. Current medical research indicates that such patients should have experienced one or both of the following:

- At least one episode of a cardiac arrest, presumably due to a ventricular tachyarrhythmia as evidenced by resuscitation using a transthoracic defibrillator. The ventricular tachyarrhythmia should not be caused by an acute myocardial infarction.
- Recurrent, sustained hemodynamically compromising ventricular tachycardias, in the absence of a prior cardiac arrest, that occur spontaneously or can be induced.

Prior to implant, patients should undergo a complete cardiac evaluation, including extensive electrophysiologic testing. Also, extensive electrophysiologic evaluation and testing of the safety and efficacy of the proposed tachyarrhythmia therapies are recommended during and after the implantation of the AMD.

Before the AMD is permanently programmed for automatic detection and delivery of any tachyarrhythmia therapy, the patient should have demonstrated a satisfactory response to the proposed therapy.

Contraindications

The AMD is contraindicated for patients with:

- Transient ventricular tachyarrhythmias due to reversible causes, such as drug intoxication, electrolyte imbalance, sepsis, or hypoxia.
- Transient ventricular tachyarrhythmias due to other factors, such as myocardial infarction and electrocution.

Because of the potential for damage to the AMD and/or induction of life-threatening arrhythmias, the use of the following techniques and/or therapies is contraindicated in patients who have an AMD:

- Magnetic Resonance Imaging (MRI).
- Hydraulic Shock-wave Lithotripsy.

Warnings

The Medtronic® Arrhythmia Management Device (the “AMD”) and the Medtronic Implantable Leads (the “Leads”) are implanted in the extremely hostile environment of the human body. This environment places severe limitation on the design and function of the AMD and Leads. These limitations unavoidably reduce the effectiveness and longevity of the AMD and Leads despite the exercise of due care in design, component selection, manufacture, and testing prior to sale.

The AMD includes a power source which will ultimately cease to function due to exhaustion or premature failure, thereby necessitating removal of the AMD. The Leads are necessarily very small in diameter and very flexible, which unavoidably increases the likelihood of breakage or breach of their insulation. Other reasons for failure of the AMD or Leads include but are not limited to: body rejection phenomena; physiological variations in patients; medical complications, including antiarrhythmic drugs; Lead displacement; Lead fracture; fibrotic tissue formation; erosion of the AMD or Lead through body tissue; infection; perforation of an artery or heart; random component failure; or interference from transmitters, tools, appliances, instruments, equipment, electrocautery, external defibrillators or other devices which use electricity, ionizing radiation, or electromagnetic wave transmission.

Complications which may be associated with the use of the AMD and Leads include but are not limited to: failure to detect ventricular tachycardia or ventricular fibrillation; failure to terminate ventricular tachycardia or ventricular fibrillation; delivery of a pacing or shock therapy when no ventricular arrhythmia is present, which could precipitate an episode of ventricular tachycardia or ventricular fibrillation; acceleration of a ventricular arrhythmia; failure to capture after a shock delivery; constrictive pericarditis; discomfort or pain during or following the delivery of electrical shock; or tissue or muscle burns at the site of the electrodes.

Consequently, no representation or warranty is made that failure or cessation of function of the AMD or Leads will not occur, that the body will not react adversely to the implantation of the AMD or the Leads, that medical complications will not follow the implantation of the AMD or the Leads, that the AMD and Leads will effectively restore adequate cardiac function or that implantation of the AMD and Leads will prevent sudden death. See the Medtronic Warranty, packaged with the AMD, for the terms and conditions of the warranty.

Electrocautery

Electrosurgical units should never be used in the vicinity (i.e., 15 cm [six inches] or closer) of the AMD and its associated lead system. Currents generated from electrosurgical units may cause permanent loss of output, induce ventricular fibrillation, or reset programmed parameters in these units (see "Effects of Electrocautery and Defibrillation" on page 1-17). Where alternatives to electrocautery are available, these should be used.

Charge Circuit Timeout

If the charging time exceeds 30 seconds, the programmer displays a **Charge Circuit Timeout** message. If this occurs, replace the AMD to protect against potential loss of device function (see "End of Life (EOL) Indicators" on page 13-4).

Precautions

Diathermy

Therapeutic diathermy should not be used at the implant site on patients who have an AMD because of possible damage to the circuitry due to heating effects on the AMD.

Defibrillation

The AMD may be damaged by direct or transthoracic defibrillatory discharges. When performing direct heart defibrillation, do not directly contact the exposed metal surface of any electrode with the paddles. When performing transthoracic defibrillation, do not place a paddle directly over the AMD. Interrogate the AMD after the use of direct or transthoracic defibrillation to determine the functional integrity of circuits and programmed parameters. Reprogramming may be necessary.

Implanted or Temporary Pacemakers

Generally, explant any previously implanted pacemaker (especially unipolar) or tachyarrhythmia device. The output pulses of an implanted unit may adversely affect the tachyarrhythmia detection capabilities of the AMD. If the pacing lead(s) must be abandoned, rather than removed, it (they) should be capped to ensure it (they) will not become a pathway for currents to or from the heart. However, if a patient requires a separate atrial or dual chamber pacemaker for hemodynamic reasons, use only a bipolar pacemaker and test the AMD to determine if output pulses from the bradycardia unit will be sensed by the AMD. Pacemakers with a programmable polarity option must be programmed to the bipolar configuration. Explant any programmable polarity pacemakers that have the potential to be reset to the unipolar configuration by high-voltage shocks. If a temporary pacemaker is required for patient management these warnings and precautions also apply.

Inhibition of Bradycardia Pacing by Telemetry

Telemetry communication with the AMD may cause inappropriate sensed events resulting in a brief inhibition of bradycardia pacing therapy. Removing the programming head restores the AMD to normal operation.

Use of a Magnet

Use only a Medtronic magnet (Part No. 174105) or programming head over the AMD. Use of multiple magnets to extend the telemetry range is not recommended.

Positioning a magnet or the programming head of the Programmer over the AMD temporarily suspends automatic tachyarrhythmia detection and makes the AMD subject to programming. Using the **SUSPEND Dx** function on the Programmer also temporarily suspends detection. Placing a magnet over the AMD does not inhibit bradycardia therapy.

Power-On Reset

Certain conditions, (including but not limited to: exposure to EMI, electrocautery or transthoracic defibrillation) may lead to an electrical reset of the AMD. The table in the Specifications lists the settings the AMD is reset to when a "power-on reset" (POR) occurs (see page S-17). Always interrogate the AMD at the beginning and end of each follow-up session to verify and document that the programmed status of the AMD is as desired. The AMD may be reprogrammed to desired parameters after the source of interference is removed.

If a POR has occurred, then the **POWER ON RESET** message should be cleared from the AMD memory and the AMD reprogrammed to desired parameters.

Preventing Accidental Exposure to Maximum Voltage

After an electrical reset of the AMD, VF detection and therapies are programmed ON at the settings given in the Specifications (page S-17). To prevent an accidental discharge during implantation or explantation, the AMD should be programmed so that all automatic tachyarrhythmia detection features are OFF.

In the event of a patient's death while the AMD is implanted, the AMD should be explanted and returned to Medtronic. Prior to the explant procedure, all automatic tachyarrhythmia detection features must be programmed OFF to prevent the delivery of potentially hazardous shocks to medical or mortuary personnel. Medtronic requests that medical personnel interrogate the AMD and print a full report before turning off detection and explanting the AMD.

Disease Progression, Detection, and Automatic Therapies

The physician should be aware that, even when there has been a satisfactory response to tachyarrhythmia therapies during clinically conducted EP studies, underlying or accompanying disease or change in antiarrhythmic drug therapy may over time alter the heart's electrophysiologic characteristics. Thus, over time, the programmed automatic therapies may not only be ineffective but also deleterious to the patient (e.g., initiate an atrial tachyarrhythmia or accelerate a ventricular tachycardia to flutter or fibrillation). Regular testing is recommended to confirm that the programmed parameter values are appropriate.

Repeated, Multiple Tachycardia Episodes

The physician must weigh the risks versus the benefits for patients who display a history of repeated and multiple ventricular tachycardia episodes. Use discretion in the treatment of such episodes, since it may quickly deplete the battery of the device. The device has a finite capacity for its high voltage therapies. The use of antitachycardia pacing level therapies will not appreciably alter the device's longevity.

Nonsterile Package

The sterile package should be inspected prior to opening. If the seal or package is damaged, contact your local Medtronic representative.

Damage to a Device Prior to Implantation

The device should not be implanted if dropped on a hard surface from a height of 30 cm (12 inches) or more.

Infrequent Charging of the High-voltage Capacitors

Infrequent charging of the high-voltage capacitors may cause the charging period to be longer than desired. Every six months, the capacitors should be conditioned manually if the device has not gone through a charge to 27 joules.

Random Failures

All devices will ultimately cease to function due to normal depletion of the battery and may also fail at any time due to random component or battery failure which cannot be predicted prior to their occurrence. Also, the system may cease to function at any time due to lead-related problems such as dislodgement, fracture, fibrotic tissue formation, elevated thresholds, or medical complications.

Electromagnetic Interference (EMI)

Exposure to EMI may, under certain circumstances, prevent arrhythmia detection or cause the device to falsely detect an arrhythmia and deliver an unneeded therapy. The delivery of the therapy could, in turn, provoke an actual tachyarrhythmia. Additionally, since the device communicates with the programmer by means of radio frequency telemetry, EMI may cause short telemetry interruptions. Keep patients away from EMI sources, when and as long as any detection criteria are enabled. Physicians should carefully weigh their decision to increase the device's sensitivity, as it will increase the susceptibility to EMI sources. EMI sources include, but are not limited to, the following:

- Nuclear Magnetic Resonance Imaging (MRI) equipment
- Hydraulic shock-wave lithotripsy
- Therapeutic diathermy
- Defibrillation equipment
- Electrocautery
- High-voltage systems
- Radio transmitters
- Theft prevention equipment
- Current-carrying conductors
- High-powered electromagnetic fields

Effects of Electromagnetic Interference

The device is designed to limit the effects from most common sources of electromagnetic interference (EMI). Because many forms of EMI exist, it is impossible to characterize all of them here. In general, tachyarrhythmia detection should, if possible, be programmed OFF before subjecting the patient to procedures that induce strong electromagnetic fields.

Bipolar sensing makes the device relatively insensitive to signals of non-cardiac origin. It is important to maintain a distance no greater than one (1) cm between myocardial electrodes to minimize EMI effects. The patient should be advised to avoid strong electromagnetic fields such as those listed in Table 1-2. Such signals could be interpreted by the device as being of cardiac origin and be detected as a tachyarrhythmia with subsequent delivery of automatic therapies.

Prescribing the AMD

Precautions

Table 1-2. Precautions Against EMI Effects

Source	Effects/Precautions
Standard fluoroscopy radiation for imaging	No Effect.
Microwave diathermy/ovens	No Effect.
Therapeutic diathermy	Heating of circuitry. Must be avoided directly over the device. Program tachyarrhythmia detection OFF.
Transthoracic defibrillation (see also page 1-17)	Effectiveness of transthoracic defibrillation may be affected by the implanted device system; possible circuit damage or loss of output if ≥ 400 J or within 15 cm of the device; increased pacing threshold; decreased R-wave amplitude; resetting of programmed parameter values (see "Power-On Reset" on page 1-9).
Direct defibrillation (see also page 1-17)	Effectiveness of direct defibrillation may be affected by the implanted device system; potential circuit damage to the device, loss of output, increased pacing threshold, decreased R-wave amplitude, resetting of programmed parameter values. Avoid direct contact of the paddles with the exposed coils of the patch electrodes.
Electrosurgical cautery (see also page 1-17)	Possible triggering of automatic detection and/or therapies; within 15 cm of the device system, the complications may include: potential circuit damage to the device, loss of output, increased pacing threshold, decreased R-wave amplitude, or resetting of programmed parameter values. Program tachyarrhythmia detection OFF to avoid inadvertent detection.

Table 1-2. Precautions Against EMI Effects

Source	Effects/Precautions
Ionizing radiation	Possible damage to circuitry. Should be avoided or device shielded; see "Hospital or Medical Environment" on page 1-16. May mimic R-waves and inhibit output or initiate automatic detection and therapies. Program tachyarrhythmia detection features OFF to avoid inadvertent detection.
Domestic electrical equipment, car engine, cellular telephones, airport screening equipment	No adverse effect with conventional, properly grounded and operating devices. Excessive levels of EMI may cause tachyarrhythmia detection.
Pulsed energy; leakage current	May mimic R-waves and inhibit output or cause tachyarrhythmia detection.
Continuous strong interference	May mimic R-waves and inhibit output or cause tachyarrhythmia detection.
Continuous strong magnetic field	Undesired suspension of tachyarrhythmia detection; possible damage to device circuitry, if charging occurs.
Metal portions of the electrodes touching each other	A short circuit may occur during defibrillation or cardioversion resulting in permanent damage to the device's high energy output circuitry.

Hospital or Medical Environment

Exposure to normal diagnostic levels of X-ray and fluoroscopic radiation should not affect the device.

Telemetry communication with the device may cause inappropriate sensed events, resulting in a brief inhibition of bradycardia therapy until the programming head is removed.

The AMD should not be directly irradiated by therapeutic levels of ionizing radiation (such as produced by cobalt or linear accelerators used for cancer treatment) because of risk of permanent damage to the device's circuitry. If such therapy is required in the vicinity of the device, the device should be shielded (with tachyarrhythmia detection OFF) and its operation and various functions confirmed following treatment.

Effects of Electrocautery and Defibrillation

The use of electrocautery within 15 cm, or direct defibrillation within 3 cm, could cause permanent damage to the AMD or the implanted leads. Transthoracic defibrillation also could cause a temporary loss of sensing and/or pacing capture due to localized tissue damage.

Under certain conditions, the use of direct defibrillation or electrosurgical cautery in the vicinity of the AMD system could cause the device to be set to its reset parameter values.

Program tachyarrhythmia detection features OFF during electrosurgical cautery to avoid triggering automatic therapy.

After direct or transthoracic defibrillation, validate the functional integrity of the AMD circuits and programmable parameters.

Always interrogate the device at the beginning and end of each follow-up session and print a full report to verify and document that the programmed status of the device is as desired.

Home or Job Environment

The device should not be affected by the normal operation of electrical equipment such as household appliances, electrical machine shop tools, microwave ovens, spark-ignited internal combustion engines, radio frequency transmitting systems, or microwave frequency transmitting systems.

Such effects normally will not be observed if proper electrode spacing (e.g., transvenous bipolar sensing) is provided at implant.

Medtronic should be consulted when device wearers will be in areas where contact with current-carrying conductors is possible or when they must come near high-powered, electromagnetic fields radiated by arc-welding units, induction furnaces, resistance welders, etc.

Cellular Phones – Recent studies have indicated there may be a potential interaction between cellular phones and implantable defibrillator operation. Potential effects may be due to either the radio-frequency signal or the magnet within the phone and could include inhibition or delivery of additional therapies when the phone is in close proximity (within six inches) to the implanted defibrillator. It is important to note that, based on testing to date, any effect resulting from an interaction between cellular phones and implanted defibrillators is temporary. Because of the great variety of cellular phones and the wide variance in patient physiology, an absolute recommendation to cover all patients cannot be made. The following information provides a general guideline to patients having an implanted defibrillator who desire to operate a cellular phone.

- Maintain a minimum separation of six inches (15 centimeters) between a hand-held personal cellular phone and the implanted device. Portable and mobile cellular phones generally transmit at higher power compared to hand-held models. For phones transmitting above three watts, a minimum separation of twelve inches (30 centimeters) between the antenna and the implanted device is advised.
- Patients should hold the phone to the ear opposite the side of the implanted device. Patients should not carry the phone in a breast pocket or on a belt over, or within six inches of, the implanted device, because some phones emit signals when they are turned on but not in use (i.e., in the Listen or Standby mode). Storing the phone in a location opposite the side of the implant is recommended.

Adverse Events

The following adverse events may arise during and after implantation of a device: myocardial irritability at implant, which might cause premature ventricular contractions (PVCs), supraventricular tachycardia, or fibrillation; cardiac tamponade or loss of sensing due to perforation of the myocardium at implant; acute hemorrhage due to venous perforation; infection; thrombus formation and subsequent pulmonary embolization caused by the presence of intravascular leads; loss of system function due to battery failure or other component failure; inability to reprogram the device because of programmer failure; false sensing, inappropriate pulsing and/or inhibition of normal electrical conduction due to dislodged or fractured leads, case fracture, or electronic component failure; interruption of desired function due to electrical or magnetic interference, including nuclear magnetic resonance (NMR) and diathermy and lithotripsy when used near the site of the device and leads, and system failure due to ionizing radiation; erosion or extrusion of the device; fibrotic tissue growth; fluid accumulation; keloid formation; and formation of hematomas or cysts.

Potential Adverse Events

Potential adverse events include, but are not limited to, the following:

- Body rejection phenomena, including local tissue reaction
- Muscle and nerve stimulation
- Pericarditis
- Infection
- Lead dislodgment
- Erosion of the AMD, lead, or adapter through the skin
- Adverse psychological effects, which may include psychological intolerance to the AMD, imagined pulsing, dependency, fear of inappropriate pulsing, and fear that pulsing capability may be lost.

Storage and Handling

Do not implant the AMD if the package is damaged.

The temperature range for transportation and storage is from -18°C (0°F) to $+55^{\circ}\text{C}$ (131°F).

Exposure to temperatures below $+10^{\circ}\text{C}$ (50°F) can cause the AMD charge time to be extended. The charge time will stabilize once the AMD is at room temperature for at least one hour.

Exposure to temperatures below -18°C (0°F), or intense electrical interference, may cause the AMD's parameter settings to change to electrical reset conditions. (See "Emergency Settings" on page S-16 for electrical reset parameters.)

Dropping the AMD onto a hard surface (e.g., from a height of 30 cm [12 inches] or more onto a concrete floor) could damage the AMD. Should this occur, do not implant the AMD.

Resterilization

Note: These guidelines for resterilization of the AMD also apply to the white handled torque wrench packaged with the AMD.

Medtronic has sterilized the AMD with ethylene oxide prior to shipment. The sterile package is designed to maintain the AMD in a sterile condition. If the AMD was not used, it may be resterilized in ethylene oxide.

Do not autoclave or sterilize the AMD by gamma irradiation.
Do not attempt to clean the AMD in ultrasonic cleaners.

Resterilization of an AMD does not change the "use before" date established at the time of manufacture.

Emergency Therapy

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Emergency Therapy Overview

The AMD provides the following Emergency functions:

- Ventricular defibrillation therapy
- Ventricular cardioversion therapy
- Maximum output VVI pacing.

To deliver an Emergency therapy, the programming head must be positioned over the AMD.

Ventricular defibrillation is the default Emergency therapy, and 27 joules is the default stored energy. When you select **EMERGENCY** and **DELIVER**, the AMD charges and delivers a biphasic 27 joule shock along the CAN>RVC pathway.

If you select a different defibrillation energy, the programmer resets the energy to 27 joules the next time you select Emergency. Emergency Ventricular Cardioversion values remain as selected for the duration of the session.

Aborting the Therapy – As a safety precaution, the programmer also displays an **ABORT** button which immediately terminates any emergency therapy in progress.

Effect on System Operation

The AMD suspends its automatic detection features when Emergency ventricular defibrillation or cardioversion therapies are delivered. Detection is not suspended during Emergency VVI pacing. Removing the programming head or pressing **RESUME Dx** re-enables detection.

On-Screen and Display Panel Buttons

The on-screen **EMERGENCY** button and the red mechanical "EMERGENCY" button on the programmer display panel are equivalent at all times.

Red "Emergency" Button



*Functions the same as on-screen **EMERGENCY** at all times.*

The on-screen **DELIVER** button and the yellow-on-blue mechanical "DELIVER" button on the programmer display panel are equivalent during Emergency operations only. The mechanical "DELIVER" button operates only during Emergency operations.

*Yellow-on-Blue
"Deliver" Button*



*Functions the same as on-screen **DELIVER**, but only during Emergency functions.*

Temporary Parameter Values

Emergency ventricular cardioversion and defibrillation therapies use *test values* that do not change the AMD's permanently programmed parameters.¹ Test values are not in effect until you begin the temporary operation by selecting **DELIVER**. After the therapy is complete, the AMD reverts to its permanently programmed values.

1. Delivery of Emergency VVI Pacing permanently changes the programmed bradycardia pacing values to those used during emergency pacing (see page 2-6).

Emergency Ventricular Defibrillation

◆ **How to Deliver Emergency 27 Joule Defibrillation**

1. Position the programming head over the AMD.
2. Select **EMERGENCY**. The programmer displays the Emergency Defibrillation Therapy screen (shown below).
3. Select **DELIVER**.

If delivery is not confirmed, verify that the programming head is properly positioned and select **DELIVER** or **RETRY**.

◆ **How to Change the Defibrillation Energy**

1. From the Emergency Defibrillation screen, select **ENERGY (J)**.
2. Select a new stored energy value from the window.
3. Select **DELIVER**.

Emergency
V-Defibrillation Energy
(circled)

The screenshot shows a medical device screen titled "EMERGENCY THERAPY:". In the top right corner is a button labeled "EXIT EMERGENCY". Below the title are three buttons: "DEFIBRILLATION", "CARDIOVERSION", and "VVI PACING". The "DEFIBRILLATION" button is highlighted. Below these buttons, the following settings are displayed: "Energy(J):" with the value "27" circled, "Waveform: BIPH", and "Pathway: CAN-RUC". At the bottom of the screen, a black bar contains the text "Select DELIVER to defibrillate now."

Emergency Ventricular Cardioversion

◆ How to Deliver Emergency Ventricular Cardioversion

1. Position the programming head over the AMD.
2. Select **EMERGENCY**.
3. Select **CARDIOVERSION**. The programmer displays the Emergency Cardioversion Therapy screen (shown below).
4. Accept the cardioversion energy shown on the screen, or select **ENERGY (J)**: and select a new value from the window.
5. Select **DELIVER**.

If delivery is not confirmed, verify that the programming head is properly positioned and select **DELIVER** or **RETRY**.

Emergency
V-Cardioversion Energy
(circled)

The screenshot shows a device screen with a black header bar containing the text "EXIT EMERGENCY" in white. Below the header, the text "EMERGENCY THERAPY:" is displayed. Underneath, there are three buttons: "DEFIBILLATION", "CARDIOVERSION", and "VVI PACING". The "CARDIOVERSION" button is highlighted. Below these buttons, the following information is displayed: "Energy(J): 27" (where 27 is circled), "Waveform: BIPH", and "Pathway: CAN>RUC". At the bottom of the screen, a black bar contains the white text "Select DELIVER to cardiovert now."

Emergency VVI Pacing

◆ How to Deliver Emergency VVI Pacing

1. Position the programming head over the AMD.
2. Select **EMERGENCY**.
3. Select **VVI PACING**. The programmer displays the Emergency VVI Pacing Therapy screen (shown below).
4. Select **PROGRAM**. A successful programming sets the permanently programmed bradycardia pacing values to the values shown on the Emergency VVI Pacing Therapy screen.

If programming is not confirmed, verify that the programming head is properly positioned and select **PROGRAM** or **RETRY**.

Fixed
Emergency VVI
Pacing Parameters

Overview of Prevention, Detection, and Therapy

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Cardiac Interval Measurement

The AMD measures cardiac cycle lengths in increments of 10 ms. For event classification and for calculating interval averages, measurements are truncated to a 10 ms multiple. For example, 457 ms is recorded as 450 ms.

However, the AMD's output pulses are synchronized by rounding to the nearest 10 ms. For example, when a bradycardia pacing interval for a rate of 70 ppm is computed as 857 ms, the pulse is scheduled for delivery at 860 ms.

Atrial Arrhythmia Prevention

The AMD has three pacing-level features intended to prevent the incidence of atrial arrhythmias.

Atrial pacing – DDD, DDI and AAI modes are available. By maintaining AV synchrony, atrial pacing helps to improve hemodynamics.

Atrial Rate Stabilization (A-A Stabilization) – Atrial Rate Stabilization is a programmable feature available in DDD and AAI modes designed to prevent the onset of atrial tachyarrhythmias by eliminating the long pause that typically follows a premature atrial contraction (PAC). Such short-long sequences of atrial cycle lengths have been observed to precede the onset of some spontaneous atrial tachyarrhythmias.

High-Rate Overdrive DDI Pacing – The Mode Switch feature can be used to effect high-rate overdrive DDI pacing immediately after AF/AT termination. This is accomplished by programming a high DDI Rate and an appropriately long Switchback Delay. For example, a patient can be paced at a DDI Rate of 80 ppm for a Switchback Delay of 2 minutes in order to overdrive suppress a recurrent, non-sustained atrial tachyarrhythmia.

Dual Chamber Detection

The AMD receives an electrogram (EGM) signal through its atrial and ventricular sensing leads. It measures the time between sensed and paced atrial events to determine the median atrial cycle length, and between sensed and paced ventricular events to determine the ventricular cycle length. The AMD also measures and analyzes the relationship between P:R and R:P intervals to enhance the classification specificity for atrial and ventricular tachyarrhythmias.

The AMD utilizes two independently functioning dual chamber detection algorithms to classify tachyarrhythmias: a ventricular tachyarrhythmia detection algorithm and an atrial tachyarrhythmia detection algorithm.

The AMD gives priority to the detection and treatment of ventricular tachyarrhythmias. An atrial tachyarrhythmia cannot be detected unless the ventricular tachyarrhythmia detection algorithm has first determined that the rhythm is not VF or VT (see Figure 3-1).

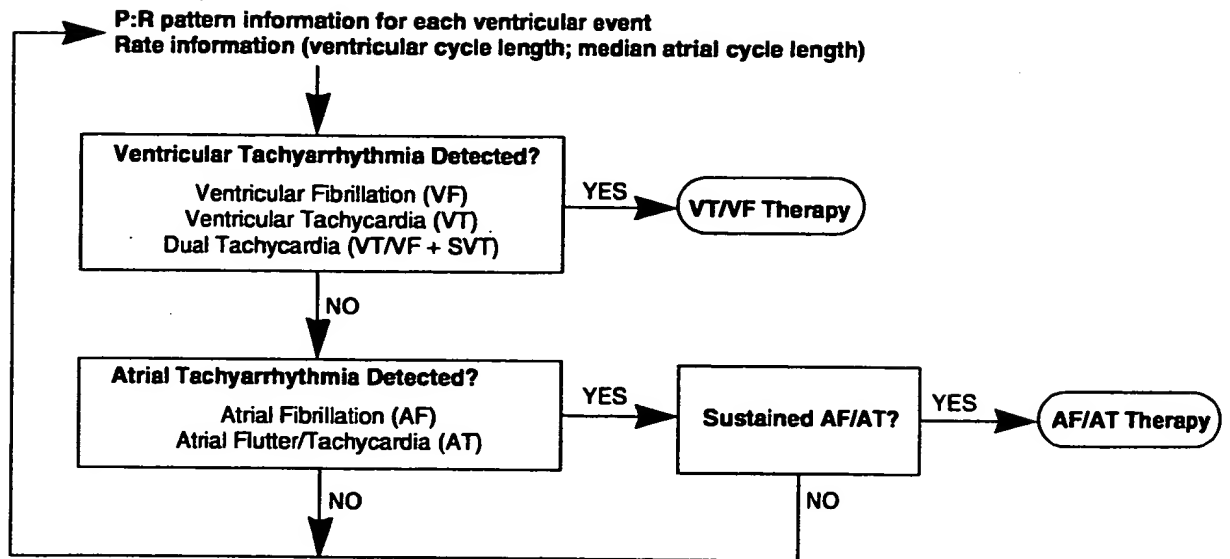


Figure 3-1. Detection and Therapy Flow Diagram

VT/VF Detection and Redetection

Dual chamber VT/VF detection combines P:R pattern information with rate information to determine if a rhythm is a dual tachycardia (e.g., VF or VT with a concurrent SVT), a rapidly conducted SVT, or VT or VF.

Dual chamber VT/VF detection is designed to improve ventricular tachyarrhythmia detection specificity by withholding VT or VF detection for rapidly conducted supraventricular tachycardias (SVTs) that might otherwise be inappropriately detected as VT or VF based on rate criteria alone.

The AMD applies up to three independently programmable (ON/OFF) dual chamber VT/VF detection criteria to identify several classes of rapidly conducted SVTs (atrial fibrillation/flutter, sinus tachycardia, or other 1:1 SVTs; see "Dual Chamber VT/VF Detection Criteria" on page 6-16). If a rhythm fulfills any of these programmed criteria, the AMD withholds ventricular therapy, and monitors the rhythm for possible atrial tachyarrhythmia detection and therapy.

If the ventricular cycle length falls within one of the programmed ventricular tachyarrhythmia detection zones, the device marks that cycle as a VF or VT event and increments the associated ventricular tachyarrhythmia event counter in the AMD memory. If the VF or VT event counter reaches the programmed Number of Intervals to Detect (NID) or the Combined Number of Intervals to Detect (CNID), and the rhythm is not classified as a rapidly conducted SVT, a VT or VF episode is detected, and the appropriate VT or VF therapy is delivered (see Figure 3-1).

After the therapy delivery, if the VF or VT event counter reaches the programmed Number of Intervals to Redetect (RNID) or the Combined Number of Intervals to Redetect (RCNID), the episode is redetected.

Note: The dual chamber VT/VF detection criteria are not applied during VT/VF redetection.

AF/AT Detection and Redetection

Dual chamber AF/AT detection combines P:R pattern information with rate information to detect and classify non-1:1 atrial tachyarrhythmias such as atrial flutter/tachycardia (AT) and atrial fibrillation (AF).

If the ventricular tachyarrhythmia detection algorithm has not classified a rhythm as VF or VT, the rhythm is evaluated by the atrial tachyarrhythmia detection algorithm.

Preliminary AF/AT Detection – If the median atrial cycle length falls within one of the programmed atrial tachyarrhythmia detection zones, and the AF/AT Evidence Counter has detected 32 ventricular events in which the P:R pattern supports the presence of an atrial tachyarrhythmia (i.e., greater than 1:1 A:V conduction, without far-field R-wave sensing), preliminary AF/AT detection occurs and the AMD starts a sustained AF/AT duration timer.

Sustained AF/AT Detection – If AF/AT episode duration exceeds the programmed duration required to initiate therapy (programmable duration values: 0 min; 1 min – 24 hours; independently programmed for pacing and defibrillation therapies) the AMD detects a sustained episode and can initiate the first applicable programmed AF or AT therapy.

After the therapy delivery, if the preliminary detection criteria are met again, the episode is redetected.

Therapy

Atrial Tachyarrhythmia Therapy

The AMD provides five therapies for atrial tachyarrhythmias:

- A-Burst+ pacing (ATP)
- A-Ramp pacing (ATP)
- A-50 Hz Burst (High Frequency) pacing
- Automatic atrial defibrillation
- Patient-activated atrial defibrillation

Each detected AF episode can be treated with a 50 Hz Burst pacing therapy and up to five automatic atrial defibrillation shocks. Each detected AT episode can be treated with up to three atrial pacing therapies, and up to three automatic defibrillation shocks.

The patient can request a defibrillation shock using a hand-held Patient Activator. A patient-activated defibrillation shock is delivered only if the AMD confirms that either AF or AT is present, and only if it can synchronize to a ventricular event.

Atrial Therapy Sequencing Parameters

AF/AT Sustained Duration Criterion – The duration of sustained AF/AT required to initiate atrial pacing therapies and atrial defibrillation therapies are independently programmable in the AMD.

When preliminary AF or AT detection occurs, a sustained duration timer starts. Automatic AF or AT therapy is withheld until the AF/AT episode duration exceeds the programmed duration required to initiate pacing or defibrillation therapy.

The sustained duration timer continues during AF/AT therapy delivery and redetection. It is reset to zero when AF/AT episode termination is detected.

Time to Stop Therapy – The AMD suspends all AF and AT therapies for the duration of an AF/AT episode if the sustained duration timer exceeds the programmed Time to Stop Therapy.

A-Defib Daily Availability Window – You can program the AMD to deliver atrial defibrillation therapies only during selected hours of the day or night. You can also limit the number of shocks the AMD can deliver during a 24-hour cycle.

Atrial Therapy Sequencing

Once AF/AT episode duration exceeds the programmed duration required to initiate pacing or defibrillation therapy, the AMD can initiate the first programmed pacing or defibrillation therapy for AF or AT, based on the current rhythm classification. If the AF/AT episode is subsequently redetected, and the episode duration exceeds the programmed duration required to initiate the applicable pacing or defibrillation therapy, the next programmed therapy can be initiated. This progression continues until the AMD confirms termination of the episode, or delivers all the therapies programmed for that class of atrial tachyarrhythmia.

Note: Depending on the programmed Sustained Duration values for pacing and defibrillation therapies, atrial therapies may not be delivered in the order they are listed on the programmer screen. Atrial therapies are delivered according to the length of the episode and the rhythm classification during the episode.

Ventricular Tachyarrhythmia Therapy

The AMD offers five therapies for ventricular tachyarrhythmias (and dual VT/VF + SVT tachyarrhythmias):

- V-Burst pacing (ATP)
- V- Ramp pacing (ATP)
- V-Ramp+ pacing (ATP)
- Ventricular cardioversion
- Ventricular defibrillation

Each detected VF episode can be treated with up to six defibrillation shocks. Each detected VT episode can be treated with up to six ventricular pacing and/or cardioversion therapies.

Ventricular Therapy Sequencing

Once a ventricular tachyarrhythmia episode is detected, the AMD delivers the first programmed therapy for that class of tachyarrhythmia. If the episode is subsequently redetected, the next programmed therapy is delivered. This progression continues until the AMD confirms termination of the episode, or delivers all the therapies programmed for that class of ventricular tachyarrhythmia.

Suspension of Detection and Therapies

When one of the AMD's detection or therapy features is "suspended," the function is temporarily inactivated.

Automatic Suspension of Detection

Atrial and ventricular tachyarrhythmia detection is temporarily suspended during:

- Magnet application, unless **RESUME Dx** is programmed.
- Delivery of automatic AF, AT, VF and VT therapies, including charging periods.
- Delivery of patient-activated atrial defibrillation therapies, including charging periods.
- Delivery of manual or emergency tachyarrhythmia therapies. Removing the programming head or pressing **RESUME Dx** re-enables detection.

VT Detection is temporarily suspended during the first 17 ventricular events (paced and sensed) after an automatic ventricular defibrillation therapy.

AF and AT Detection are temporarily suspended during the first 16 ventricular events (paced and sensed) after an A-50 Hz burst pacing therapy.

Automatic Suspension of Therapy

Atrial therapies are suspended until atrial termination if an episode's duration exceeds the programmable Time to Stop Therapy.

AF therapies are suspended for four minutes following the delivery of an automatic A-Burst+ or A-Ramp pacing therapy for AT.

Manually Suspending Detection and Therapy

Positioning the programming head or magnet over the AMD, or executing a **SUSPEND Dx** command from the programmer, temporarily suspends the automatic detection and therapy capabilities of the AMD. In this suspended mode, the AMD does not detect tachyarrhythmias, and does not deliver prescribed automatic therapies. However, the bradycardia pacing and manually-initiated therapy capabilities of the AMD are still functional. **Suspending detection does not change the permanently programmed settings of the AMD.**

Removing the programming head or magnet from its position over the AMD restores the AMD to normal operation. The effect of a programming head, magnet, or **SUSPEND Dx** command can also be canceled by executing a **RESUME Dx** command from the programmer. If automatic detection is enabled, a **RESUME Dx** command causes the AMD to resume automatic detection even while the programming head or magnet is in position over the AMD.

Disabling of Detection and Therapies

“Disabled” is a programmed state in which the detection or therapy feature is not available (OFF condition). These functions can only be re-enabled through the Programmer.

Automatic Disabling of Detection and Therapies

AF, AT, and VT Detection are disabled whenever the AMD resets, due to an electrical reset or a detected memory error. When the AMD resets, it functions as a simple ventricular defibrillator (see “Emergency Settings” on page S-16 for electrical reset parameters).

All automatic therapies are automatically disabled whenever three consecutive 30-second charge intervals have failed to reach the programmed energy level (see “Charging Period” on page 8-10).

All AF and AT therapies are disabled if VF or VT is detected immediately following an automatic or patient-activated AF or AT therapy delivery.

Manually Disabling Detection and Therapies

To disable the automatic detection and therapy functions of the AMD, these functions must be programmed OFF via the programmer.

1. Select the Detection screen from the **PARAMETERS** menu.
2. Set the tachyarrhythmia Detection Enable parameters to OFF.
3. Program the AMD.

To re-enable automatic detection and therapy, reprogramming is required.

Sensing and Bradycardia Pacing

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Sensing

Proper sensing is essential for the safe and effective use of the AMD. Verify the AMD's sensing function regularly by means of Marker Channel telemetry (see "Marker Channel™ Symbols and Annotations" on page 11-24). **The AMD always senses in both chambers for purposes of tachyarrhythmia prevention and detection, regardless of the programmed Bradycardia Pacing mode.**

To help prevent undersensing of atrial and ventricular tachyarrhythmias, the AMD provides:

- Auto-adjusting atrial and ventricular sensing thresholds (see page 4-4),
- Short (30 ms) cross-chamber blanking after paced atrial and ventricular events, and
- No cross-chamber blanking after sensed atrial and ventricular events.

Programming for Appropriate Sensing

Atrial Sensing – An atrial sensitivity threshold of 0.3 mV is suggested, to maximize the probability that AF will be detected.

- Verify that the AMD does not sense far-field R-waves on the atrial leads.
- A value greater than 0.45 mV is not recommended except for testing and troubleshooting, as it may lead to undersensing and/or underdetection.
- Carefully evaluate the potential for increased susceptibility to EMI and oversensing before changing the atrial sensitivity threshold to its minimum (most sensitive) setting of 0.15 mV.

Ventricular Sensing – A ventricular sensitivity threshold of 0.3 mV is recommended, to maximize the probability that VF will be detected.

- Always verify that the AMD is sensing and detecting VF adequately. You may need to reposition or replace the ventricular sensing lead.
- A value greater than 0.45 mV is not recommended except for testing and troubleshooting, as it may lead to undersensing and/or underdetection. A value greater than 0.6 mV may be too insensitive for arrhythmia detection.
- Carefully evaluate the potential for increased susceptibility to EMI and oversensing before changing the ventricular sensitivity threshold to its minimum (most sensitive) setting of 0.15 mV.

If sensing or detection is inappropriate, program all automatic therapies to OFF until you perform verification studies. Monitor the patient continuously for life-threatening arrhythmias until you re-enable the AMD's therapies.

If you change the ventricular sensitivity threshold, re-induce VF and allow the AMD to automatically detect and treat the arrhythmia to evaluate proper sensing and detection.

Auto-Adjusting Sensitivity Thresholds

The AMD automatically adjusts its atrial and ventricular sensitivity thresholds following sensed and paced events, to reduce the incidence of R-wave sensing on the atrial sense amplifier, and T-wave sensing on the ventricular sense amplifier. The sensitivity thresholds decay exponentially (i.e., about 2/3 of the remaining decay each time constant period) to their programmed settings, beginning at the electrogram peak, or at the end of the blanking period if there is one.

Figure 4-1 illustrates how the ventricular sensitivity responds to paced and sensed events. Table 4-1 summarizes the AMD's auto-adjusting sensitivity values.

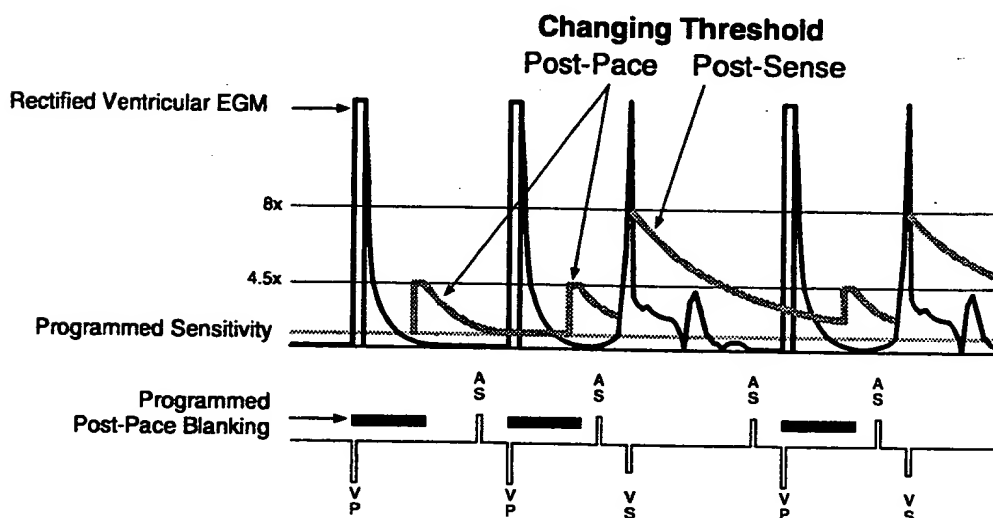


Figure 4-1. Auto-adjusting sensitivity threshold (Ventricular shown)

Table 4-1. Auto-adjusting Sensitivity Threshold Values

	Atrial Sensitivity Adjustment	Ventricular Sensitivity Adjustment
Post A-sense	75% of EGM peak (max. of 8x prog. value). 200 ms decay constant.	NONE.
Post V-sense	NONE.	75% of EGM peak (max. of 8x prog. value). 450 ms decay constant.
Post A-pace	NONE.	0.45mV.* 60 ms decay constant.
Post V-pace	0.45mV.* 60 ms decay constant.	1.8mV (max. of 4.5x prog. value). 450 ms decay constant.†

* If sensitivity is programmed to greater than 0.3 mV, the sensitivity threshold is not adjusted.

† The exponential decay continues through a subsequent pacing pulse and its programmable blanking period.

Blanking Periods

The AMD has blanking periods during which sensing is disabled. These blanking periods prevent the sensing of AMD outputs, post-pacing polarization, T-waves, and multiple sensing of the same event.

Four independently programmable blanking periods follow different pacing outputs (Table 4-2). Non-programmable blanking periods follow certain paced and sensed events, capacitor charging periods, and therapy deliveries (Table 4-3).

The blanking periods following paced events are longer than those following sensed events to avoid sensing the polarization signal on the electrodes.

Note: To enhance the reliability of sensing during tachyarrhythmias, the AMD does **not** have blanking in the opposite chamber (i.e., cross-blanking) after a **sensed** event.

Table 4-2. Programmable Blanking Periods

Atrial blanking after atrial bradycardia pace	200 – 440 ms
Ventricular blanking after ventricular bradycardia pace	200 – 440 ms
Atrial blanking after atrial ATP pace	200 – 440 ms
Ventricular blanking after ventricular ATP pace	200 – 440 ms

Table 4-3. Non-Programmable Blanking Periods

Blanking in the opposite chamber after atrial or ventricular pacing pulse	30 ms
Atrial blanking after sensed atrial event	100 ms
Ventricular blanking after sensed ventricular event	120 ms
Atrial and ventricular blanking after the end of a cardioversion or defibrillation charging period	300 ms
Atrial and ventricular blanking after delivered high voltage therapy	520 ms

Refractory Periods

The AMD has refractory periods to prevent certain pacing timing intervals from being started by inappropriate sensed signals such as retrograde P-waves, far-field R-waves, or electrical noise. Refractory periods also prevent potentially arrhythmogenic delivery of high voltage therapies. **Note:** Refractory periods do not affect tachyarrhythmia detection.

Programmable Refractory Periods

In the DDD mode, the **Post-Ventricular Atrial Refractory Period (PVARP)** prevents the sensing of retrograde P-waves that could initiate a Pacemaker Mediated Tachycardia (PMT). In the DDI mode, the PVARP prevents atrial inhibition from retrograde P-waves. The PVARP occurs in dual chamber modes after paced and non-refractory sensed ventricular events, and is extended after a pacemaker-defined PVC (see "PVC Response" on page 4-13).

Following a paced ventricular event, the first 30 ms of the PVARP is a non-programmable blanking period that disables atrial sensing.

The **Atrial Refractory Period (ARP)** prevents atrial inhibition due to sensed far-field R-waves or noise. The ARP occurs after paced and non-refractory sensed atrial events in the AAI mode only. Following a paced atrial event, the first portion of the ARP is a programmable Pace Blanking period that disables atrial sensing.

The **Atrial Defibrillation Ventricular Refractory Period** is used during atrial defibrillation synchronization to prevent the incidence of ventricular pro-arrhythmia.

Table 4-4. Programmable Refractory Periods

Post-Ventricular Atrial Refractory Period (PVARP)	150 – 500 ms
Atrial Refractory Period (ARP)	150 – 500 ms
A-Defib Ventricular Refractory Period (A-Defib VRP)	350 – 600 ms

Non-Programmable Refractory Periods

The Atrial Defibrillation Atrial Refractory Period and the Ventricular Defibrillation/Cardioversion Refractory Periods are applied during high voltage therapy synchronization to prevent the incidence of ventricular pro-arrhythmia.

Table 4-5. Non-programmable Refractory Periods

A-Defib Atrial Refractory Period (A-Defib ARP)	A-Defib VRP + 50 ms
Ventricular refractory period after charging ends during V-Defib synchronization	400 ms
Ventricular refractory period after ventricular sense during CV synchronization	200 ms
PVC Response PVARP (see page 4-13)	400 ms or programmed PVARP, whichever is greater

Bradycardia Pacing Operations

Pacing Rate

The AMD has two programmable rates that determine the patient's available pacing rates:

- The programmable Lower Rate is the minimum pacing rate for a given mode.
- The programmable Upper Rate is the maximum rate at which the ventricle may be paced in response to sensed atrial events in the DDD mode (i.e., upper tracking rate).

Pulse Width, Amplitude, and Pace Blanking

To help ensure consistent capture, Pulse Width, Amplitude, and Pace Blank are independently programmable for each of the following operations:

- Atrial bradycardia pacing
- Ventricular bradycardia pacing
- Atrial pacing (see "Atrial Pacing Therapies" on page 7-20)
- Ventricular antitachycardia pacing (see "Ventricular ATP Therapies" on page 8-19)
- EP Studies that incorporate pacing (see "EP Study" on page 9-1)
- System Tests that incorporate pacing (see "System Tests" on page 10-1)

Post-Shock Pacing Outputs – Pulse Width and Amplitude are fixed at 1.5 ms and 6 V, respectively, for both atrial and ventricular pacing after cardioversion and defibrillation shocks. These post-shock pacing values remain in force for 16 events after the shock, or until another therapy is started, whichever occurs first.

Paced AV (PAV) Interval

In dual-chamber pacing modes, the programmable PAV interval defines the duration from paced atrial events to paced ventricular events. The ventricle is paced after the PAV expires unless inhibited by a sensed ventricular event.

Notes: PAV duration may differ from the programmed setting due to Ventricular Safety Pacing operation (see page 4-12).

If the intrinsic AV interval is less than the PAV interval, the effective pacing rate may be faster than the programmed Lower Rate.

Sensed AV (SAV) Interval

In DDD pacing mode, the programmable SAV interval defines the duration from sensed atrial events to paced ventricular events. The ventricle is paced after the SAV expires unless inhibited by a sensed ventricular event. SAV does not apply to the DDI pacing mode.

Note: SAV maintains 1:1 A-V tracking up to the Upper Rate or the total atrial refractory period (the sum of the SAV and the PVARP). If the intrinsic atrial rate exceeds the Upper Rate, SAV duration may exceed the programmed setting due to Wenckebach operation (see page 4-11).

Upper Rate Behavior

In DDD mode, the fastest atrial rate the AMD can track is determined by the total atrial refractory period (TARP), which is the sum of the SAV and the PVARP.

2:1 Block Rate

When the intrinsic atrial interval is shorter than the TARP, some atrial events will fall within the PVARP, and therefore, will not initiate an SAV interval. At the rate at which this first occurs, *every other* atrial event initiates an SAV interval, and 2:1 block results (2:1 block rate = $60,000/\text{TARP}$).

Pacemaker Wenckebach Operation

If the 2:1 block rate exceeds the programmed Upper Rate, pacemaker Wenckebach may occur. When the intrinsic rate exceeds the Upper Rate, a pacing stimulus at the expiration of the SAV interval would violate the Upper Rate. In such a case, the AMD extends the SAV until the Upper Rate interval expires. Subsequent SAV intervals require greater extension, until an atrial event falls within the PVARP and is not tracked. The result is typically a fixed ratio between atrial and ventricular rates (e.g., 3:2, 4:3, etc.).

Ventricular Safety Pacing (VSP)



Caution: VSP should always be programmed ON for pacemaker-dependent patients.

Ventricular Safety Pacing prevents inappropriate inhibition of ventricular pacing due to ventricular oversensing. If the AMD senses a ventricular event in the first 110 ms after an atrial pace, it paces the ventricle at 110 ms (or the programmed PAV, whichever expires first). If the sensed event was, in fact, a ventricular depolarization, the ventricular pacing pulse at 110 ms falls harmlessly into the absolute refractory period of the ventricle.

VSP is available in the DDD and DDI pacing modes.

Note: For Submodel 0 devices and devices without a submodel,¹ if Ventricular Safety Pacing and Mode Switch features are both enabled, VSP will not function.

1. If applicable, the device submodel is displayed on the Serial Number screen (**PARAMETERS** menu) and the Circuit Status screen (**DATA** menu).

PVC Response

PVC Response extends the PVARP after a detected PVC (i.e., a ventricular event that follows a ventricular event, with no atrial event between them). PVC Response helps to prevent retrograde P-waves from initiating a pacemaker-mediated tachycardia. The PVARP applied after a PVC is 400 ms or the programmed value, whichever is greater (see also Note L on page S-22).

PVC Response is available only in the DDD mode, and is automatically enabled.

Note: For Submodel 0 devices and devices without a submodel,¹ if Atrial Rate Stabilization is enabled, PVC Response is OFF.

1. If applicable, the device submodel is displayed on the Serial Number screen (**PARAMETERS** menu) and the Circuit Status screen (**DATA** menu).

Mode Switch



Mode Switch is not recommended for patients with chronic, refractory atrial tachyarrhythmias.

Mode Switch is a programmable feature in the DDD mode that regularizes the ventricular rate during paroxysmal atrial tachyarrhythmias. If an inappropriately high atrial rate is detected, the AMD temporarily switches to the non-atrial tracking DDI pacing mode.



Programmable Parameters

Mode Switch Enable	ON or OFF.
DDI Rate (ppm)	Non-atrial tracking DDI pacing rate
Switchback Delay	Duration of extended DDI pacing.



How Mode Switch Works

Mode Switch pacing provides ventricular rate regularization in three phases: Delta, Dwell, and Fall. MS Delta gradually slows the pacing rate to the programmed DDI rate; MS Dwell applies during the Switchback Delay; and MS Fall returns to the atrial tracking DDD mode.

If Mode Switch is enabled and an inappropriately high atrial rate is detected (above the programmed Upper Rate, with greater than 1:1 conduction and no far-field R-wave sensing; see page 6-22), the AMD switches to the non-atrial tracking DDI mode for the duration of the high atrial rate.¹ To avoid an abrupt drop in ventricular rate, the AMD smoothly reduces the ventricular pacing rate to the programmed DDI Rate.

1. A mode switch will not occur during charging for a high voltage therapy.

When the AMD determines that the atrial tachyarrhythmia has stopped, and the programmed Switchback Delay interval has elapsed, the AMD returns to tracking the atrium in DDD mode.

Tachyarrhythmia detection and therapy occur as programmed during the Mode Switch episode.

High-Rate Overdrive DDI Pacing (Switchback Delay)

The Mode Switch feature can be used to effect high-rate overdrive DDI pacing after an atrial tachyarrhythmia episode has terminated. This is accomplished by programming a high DDI Rate and an appropriately long Switchback Delay.

For example, a patient can be paced at a DDI Rate of 80 ppm for 2 minutes (Switchback Delay) in order to overdrive suppress a recurrent, non-sustained atrial tachyarrhythmia.

Atrial Rate Stabilization

Atrial Rate Stabilization (A-A Stabilization) is a programmable feature available in DDD and AAI modes that is designed to inhibit the onset of atrial tachyarrhythmias by eliminating the long pause that typically follows a premature atrial contraction (PAC).

◆ **Programmable Parameters**

A-A Stabilization	Atrial Rate Stabilization (ARS). ON or OFF.
Increment (ms)	Pacing interval increment, per beat, during ARS pacing.
Min Intrvl (ms)	Minimum pacing interval for ARS pacing.

◆ **How Atrial Rate Stabilization Works**

Atrial Rate Stabilization is available in the DDD and AAI pacing modes. When ARS is enabled, each (non-refractory) atrial event begins an ARS escape interval equal to:

[the previous atrial interval plus the ARS Increment value].

If this escape interval expires, the AMD delivers an atrial pace and recalculates its ARS interval using the current atrial interval.

If the atrial rate is stable, the ARS escape interval does not expire. After a PAC, the ARS escape interval stabilizes the atrial rate and gradually returns it to the intrinsic or programmed rate. This prevents the 'short/long' sequences of atrial cycle lengths that have been clinically observed to precede the onset of some spontaneous atrial tachyarrhythmias.

◆ **Programming Considerations**

ARS Minimum Interval and VTDI/VFDI – To ensure reliable ventricular tachyarrhythmia detection, the AMD regulates the values you can select for the ARS Minimum Interval and the VF and VT Detection Intervals.

ARS Minimum Interval and Lower Rate – If the ARS Minimum Interval is programmed to a rate higher than the Lower Rate, the ARS Minimum Interval becomes the effective lower rate.

Atrial Rate Stabilization and PVARP/ARP – An ARS interval begins on each non-refractory atrial event; thus, a long refractory period can limit the effectiveness of the ARS feature. To ensure reliable ARS function when high atrial rates are present, the AMD regulates the values you can select for the ARS Minimum Interval and PVARP (DDD mode) or ARP (AAI mode).

Atrial Rate Stabilization and Ventricular Safety Pacing – To ensure reliable ventricular tachyarrhythmia detection if Atrial Rate Stabilization and Ventricular Safety Pacing features are both enabled, the programmer limits the values you can select for Lower Rate, Upper Rate, Pace Blank, PVARP, and PAV.

Bradycardia Pacing Parameters

Table 4-6 summarizes the AMD's programmable bradycardia pacing parameters, with a (✓) indicating the pacing modes for which each is pertinent. **Note:** Some nominally dual-chamber parameters are in effect during single-chamber pacing, because the AMD is always sensing both chambers for tachyarrhythmia detection.

Table 4-6. Pacing Parameters

PACING PARAMETER	Description	DDD	DDI	AAI	VVI
Lower Rate	Minimum pacing rate in the absence of sensed events.	✓	✓	✓	✓
Upper Rate	Maximum ventricular rate at which the atrium is tracked (i.e., Upper Tracking Rate).	✓	✓		
Atrial Sensitivity	Minimum level of electrical signal that registers as a sensed atrial event.	✓	✓	✓	✓
Ventricular Sensitivity	Minimum level of electrical signal that registers as a sensed ventricular event.	✓	✓	✓	✓
Atrial Amplitude	Voltage of atrial pacing pulses.	✓	✓	✓	
Ventricular Amplitude	Voltage of ventricular pacing pulses.	✓	✓	✓	✓
Atrial Pulse Width	Duration of atrial pacing pulses.	✓	✓	✓	
Ventricular Pulse Width	Duration of ventricular pacing pulses.	✓	✓	✓	✓
Atrial Pace Blank	The period during which the atrial sensing circuit is disabled after an atrial paced event, to avoid sensing the polarization signal.	✓	✓	✓	
Ventricular Pace Blank	The period during which the ventricular sensing circuit is disabled after an ventricular paced event, to avoid sensing the polarization signal.	✓	✓	✓	✓
PAV	Paced AV interval defining the duration from paced atrial events to paced ventricular events.	✓	✓		
SAV	Sensed AV interval defining the duration from sensed atrial events to paced ventricular events.	✓			
ARP	Atrial refractory period.			✓	
PVARP	Post-ventricular atrial refractory period.	✓	✓		

◆ **Programming Considerations**

Sensitivity – Programming the atrial and ventricular sensitivity thresholds to 0.3 mV is recommended, to ensure adequate AF and VF detection. The programmed sensitivity values apply to both tachyarrhythmia detection and bradycardia pacing. For more information, see “Programming for Appropriate Sensing” on page 4-3.

Pulse Width and Amplitude – Ensure that the pacing pulse delivers an adequate safety margin above the stimulation thresholds. The pulse width and amplitude settings affect the longevity of the AMD, particularly if the patient is dependent upon bradycardia pacing therapy. Pacing “cross-talk” can affect tachyarrhythmia detection. You should verify that there is no pacing cross-talk at the programmed pacing output settings.

Lower and Upper Rates and VTDI/VFDI – To ensure reliable ventricular tachyarrhythmia detection, the AMD regulates the values you can select for the Lower Rate, Upper Rate, VTDI, and VFDI.

Lower Rate and Ventricular Pace Blank – To ensure reliable ventricular tachyarrhythmia detection, the AMD regulates the values available for the Lower Rate and Ventricular Pace Blank.

Lower and Upper Rates, Ventricular Pace Blank, PVARP, PAV, Atrial Rate Stabilization and Ventricular Safety – To ensure reliable ventricular tachyarrhythmia detection when ARS and VSP are both ON, the AMD limits the values you can select for the Lower Rate, Upper Rate, Ventricular Pace Blank, PVARP, and PAV.

Lower Rate, ARP, PVARP, and PAV – To guard against competitive atrial pacing, the AMD regulates the values you can select for Lower Rate, PVARP, and PAV in DDD and DDI modes; and for Lower Rate and ARP in AAI mode.

Ventricular Parameters Pertinent in AAI Mode – In AAI mode, Ventricular Sensitivity, Amplitude, Pulse Width and Pace Blank are used during high voltage pulse synchronization.

DDD Mode

The DDD mode provides atrial synchronous pacing in the presence of intrinsic atrial activity; otherwise, AV sequential pacing occurs.

◆ **How to Program DDD Pacing**

1. From the **PARAMETERS** menu, select **BRADY PACING**.
2. Set **Pacing Mode:** to **DDD** and select the pertinent DDD pacing parameter values.
3. Enable/select parameters for **Mode Switch**, **A-A Stabilization**, and **V Safety Pacing**, if desired.

◆ **How DDD Pacing Works**

In the DDD mode, both chambers are paced at the programmed Lower Rate in the absence of sensed intrinsic events. A sensed atrial event inhibits atrial pacing and initiates a ventricular pace after the SAV interval. (See also "Mode Switch" and "Upper Rate Behavior" sections.) A paced atrial event initiates a ventricular pace after the PAV interval. A sensed ventricular event during either AV interval inhibits the ventricular pace.

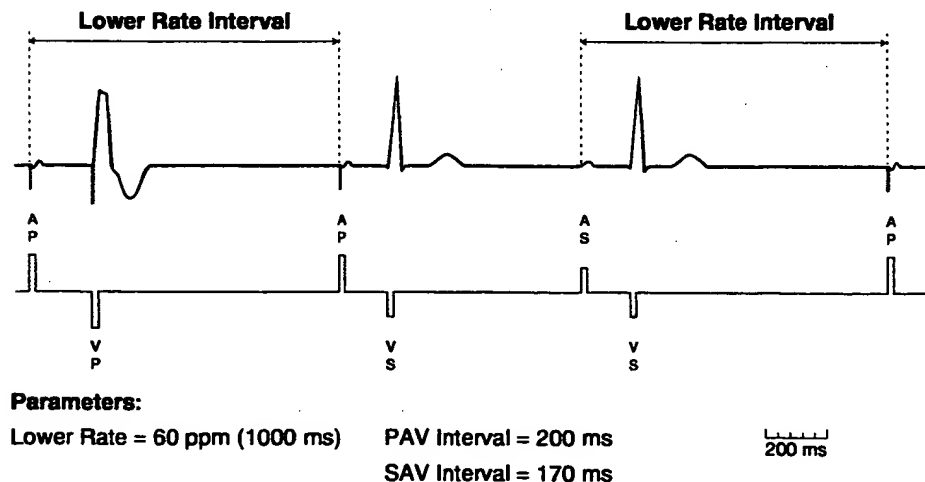


Figure 4-2. DDD Operation

DDI Mode

The DDI mode provides dual chamber A:V sequential pacing with atrial sensing, but without atrial tracking.

◆ How to Program DDI Pacing

1. From the **PARAMETERS** menu, select **BRADY PACING**.
2. Set **Pacing Mode:** to **DDI** and select pertinent parameter values.
3. Enable **V Safety Pacing**, if desired.

◆ How DDI Pacing Works

In the DDI mode, a ventricular event schedules an atrial pace at the Lower Rate minus PAV interval, and also schedules a ventricular pace at the Lower Rate. A sensed atrial event inhibits the scheduled atrial pace, but does not start an SAV interval; the ventricle is paced at the Lower Rate, unless inhibited by a sensed event. A paced atrial event initiates a ventricular pace after the PAV interval, unless inhibited by a sensed ventricular event.

Note: Atrial pacing can occur at a rate higher than the programmed Lower Rate if the intrinsic AV interval is less than the programmed PAV interval.

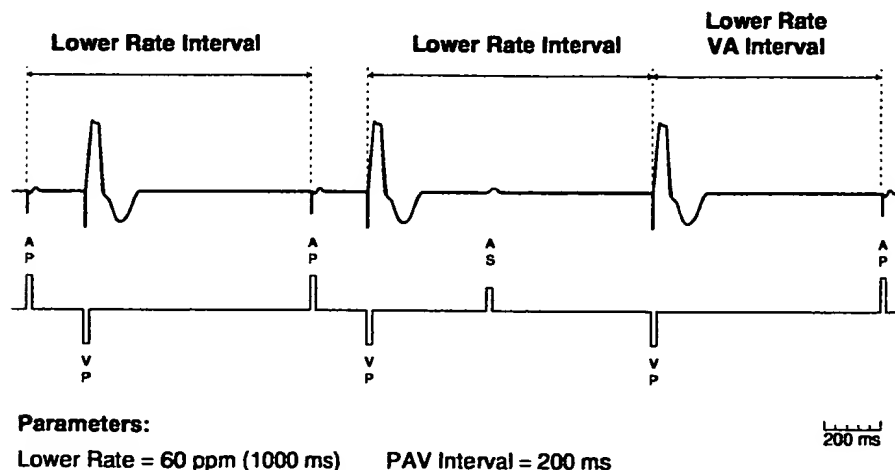


Figure 4-3. DDI Operation

AAI Mode

The AAI mode provides single-chamber inhibited atrial pacing.

◆ How to Program AAI Pacing

1. From the **PARAMETERS** menu, select **BRADY PACING**.
2. Set **Pacing Mode:** to **AAI** and select pertinent AAI pacing parameter values.
3. Enable/select parameters for **A-A Stabilization**, if desired.

◆ How AAI Pacing Works

In the AAI mode, the atrium is paced at the programmed Lower Rate unless a sensed atrial event occurs and inhibits the pacing pulse, resetting the escape interval.

Note: Ventricular sensing and tachyarrhythmia detection occur during AAI pacing.

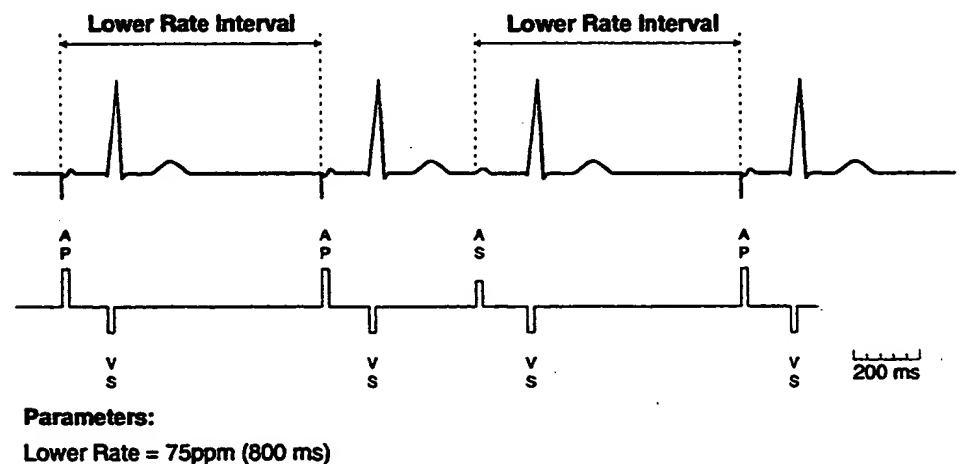


Figure 4-4. AAI Operation

Sensing and Bradycardia Pacing

VVI Mode

Dual Chamber Atrial Tachyarrhythmia Detection

5

***Atrial Tachycardia / Atrial
Fibrillation (AF/AT)
Detection 5-2***

***Non-Programmable Atrial
Detection Criteria 5-9***

***AF/AT Termination and
Redetection 5-12***

Atrial Tachycardia / Atrial Fibrillation (AF/AT) Detection

Atrial tachyarrhythmia (AF/AT) detection has two phases: preliminary detection and sustained detection.

Preliminary AF/AT detection occurs when the AF/AT Evidence Counter verifies the presence of an atrial tachyarrhythmia (see page 5-9), and the median atrial cycle length is in one of the atrial tachyarrhythmia detection zones. Preliminary AF/AT detection starts a sustained duration timer in the AMD. **Note:** There are not separate timers for AF and AT.

During **sustained AF/AT detection**, the rhythm classification is updated on each ventricular event; the AMD also monitors for AF/AT episode termination and for VT/VF detection. When the AF/AT episode duration exceeds the programmed duration required to initiate therapy, the AMD can initiate the applicable AF or AT pacing or defibrillation therapy.

See page 5-4 for a more detailed description of AF/AT detection.

◆ **Programmable Parameters**

AF ENABLE	ON or OFF.
AT ENABLE	ON or OFF.
AF INTERVAL (ms)	AFDI (Atrial Fibrillation Detection Interval). Upper limit of the AF Zone Range. Lower limit fixed at 100 ms (atrial blanking).
AT INTERVAL (ms)	ATDI (Atrial Tachycardia Detection Interval). Upper limit of the AT Zone Range.
MINIMUM AT INTERVAL (ms)	Lower limit of the AT Zone Range.
A-Sensitivity (mV)*	Minimum level of electrical signal that registers as a sensed atrial event.

* The programmed A-Sensitivity applies to tachyarrhythmia detection and bradycardia pacing.

Dual Chamber Atrial Tachyarrhythmia Detection

Atrial Tachycardia / Atrial Fibrillation (AF/AT) Detection

◆ **Programming Considerations**

AF/AT Detection can occur only if the AMD has not detected VT or VF.

To ensure VF detection backup during AF episodes, AF Detection cannot be ON unless VF Detection is also ON.

To ensure AF and VF detection backup during AT episodes, AT Detection cannot be ON unless both AF and VF Detection are also ON.

If AT and AF Detection are both enabled, there will be an "overlap zone" if the programmed **Minimum AT Interval** < **AFDI** (see Figure 5-1 on page 5-4). If an atrial arrhythmia falls into this zone, the AMD differentiates between AF and AT by applying the Atrial Cycle Length Regularity criterion (see page 5-11).

◆ **How to Program AF and AT Detection**

1. From the **PARAMETERS** menu, select **DETECTION**.
2. For AF Detection:
 - a. Set **AF ENABLE** to **ON**.
 - b. Select **AF ZONE RANGE (AFDI)** value.
3. For AT Detection:
 - a. Set **AT ENABLE** to **ON**.
 - b. Select **AT ZONE RANGE (Minimum ATInterval and ATDI)** values.
4. Set **A-Sensitivity** value.

Programmable
AF/AT Detection
Parameters
(circled)

DATA	TESTS	PARAMETERS	END SESSION	SPECIAL	PRINT
DETECTION: Select parameters and then select PROGRAM.					
	ENABLE	ZONE RANGE	SHOW PRESENT		
AF	(ON)	180 ms (270 ms)	<div style="border: 1px solid black; padding: 5px; margin: 5px;"> 180 270 170 320 </div>		
AT	(ON)	(170 ms) (320 ms)			
A Sensitivity(mV): (8.3)					

Dual Chamber Atrial Tachyarrhythmia Detection

Atrial Tachycardia / Atrial Fibrillation (AF/AT) Detection

◆ How AF/AT Detection Works

Preliminary AF/AT Detection – Preliminary AF/AT detection occurs when (1) the median atrial cycle length is in one of the atrial tachyarrhythmia detection zones (Figure 5-1), and (2) the AF/AT Evidence Counter (page 5-9) has detected 32 ventricular events in which the P:R pattern shows evidence of an atrial tachyarrhythmia.

A sustained duration timer starts at preliminary detection. (See page 7-4 for more information on the sustained duration timer.)

Table 5-1. AF/AT Detection Criteria

	Rate Information (PP Median Interval)	Pattern Information (AF/AT Evidence Counter)
AT	AT detection zone; or AF/AT overlap zone, with <i>regular</i> P-P intervals (see page 5-11).	Greater than 1:1 A:V conduction, without far-field R-wave sensing.
AF	AF detection zone; or AF/AT overlap zone, with <i>irregular</i> P-P intervals (see page 5-11).	Greater than 1:1 A:V conduction, without far-field R-wave sensing.

* If AT Detection is ON.

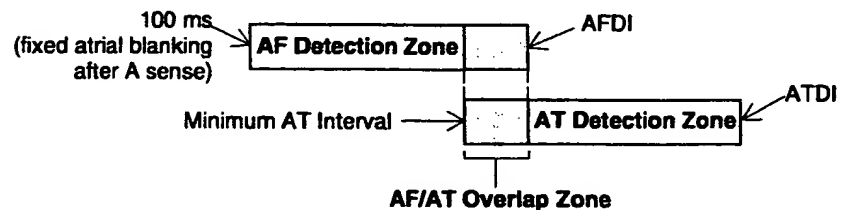


Figure 5-1. AF Detection, AT Detection, and AF/AT Overlap Zones

Dual Chamber Atrial Tachyarrhythmia Detection

Atrial Tachycardia / Atrial Fibrillation (AF/AT) Detection

Sustained AF/AT Detection – Sustained detection begins when the sustained duration timer is started. During the sustained detection period, the rhythm classification is updated on each ventricular event, and it may change between AF and AT based on the median atrial cycle length and the AF/AT Evidence Counter, which remains satisfied if its value is between 27 and 47 events (see page 5-9).

During the sustained detection period, the AMD continuously monitors for AF/AT episode termination (see page 5-13) and for VT/VF detection.

When AF/AT episode duration exceeds the programmed duration required to initiate therapy,¹ and the rhythm is classified as AF or AT, the AMD detects a sustained AF or AT episode and delivers the first applicable programmed AF or AT therapy, if all of the conditions for AF or AT therapy delivery are satisfied (see “Atrial Defibrillation Overview” on page 7-2).

AF/AT Redetection – After the therapy delivery, if the preliminary AF/AT detection criteria are met again, the AMD redetects AF/AT. If AF/AT episode duration exceeds the programmed duration required to initiate therapy (the sustained duration timer measures time since preliminary detection of the episode), and the rhythm is classified as either AF or AT, the AMD can initiate the next applicable AF or AT therapy.

Note: While an atrial episode is in progress, an atrial rhythm is “unclassified” in any of the following situations:

- During preliminary AF/AT detection;
- During AF/AT redetection, following an atrial therapy delivery; and
- During an ongoing atrial episode, if either of the atrial detection criteria is not satisfied (see Table 5-1), and AF/AT episode termination has not been detected.

See page 5-6 – page 5-8 for an example of AF/AT detection. See page 11-24 for information on atrial detection markers.

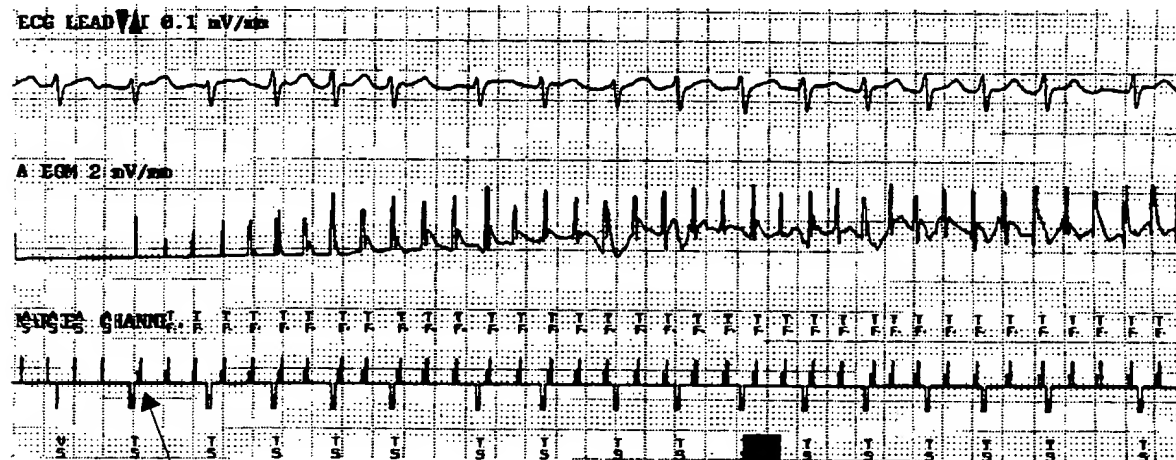
1. Independently programmed for pacing and defibrillation therapies (see page 7-4).

Dual Chamber Atrial Tachyarrhythmia Detection

Atrial Tachycardia / Atrial Fibrillation (AF/AT) Detection

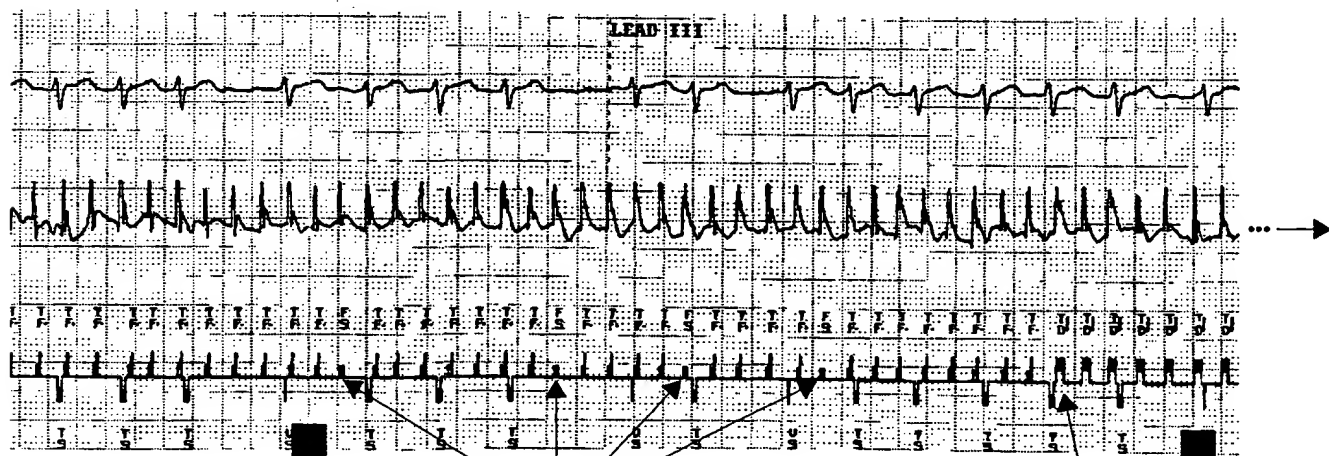
See "Supplemental Annotations" on page 11-26.

7250 3/13/96 10:45 AF/AT Dual Chamber VT/VF Detection criterion is satisfied (see page 6-19).
 CHART SPEED 25.0 mm/s Note that the criterion remains satisfied throughout the entire episode; the AMD
 60 V_AT withholds VT detection despite the VT Counter being fulfilled.



Atrial tachyarrhythmia starts.
 The median PP interval falls into AT/AF Overlap Zone (note AT Sense via AF markers).

Atrial rhythm classification — AT V_AT
 AF/AT Dual Chamber VT/VF Detection criterion remains satisfied



Occasional AF Sense markers
 among AT Sense via AF markers.

Preliminary AT Detection (32nd ventricular beat).
 See "AF/AT Evidence Counter Criterion" on
 page 5-9. Sustained detection begins.

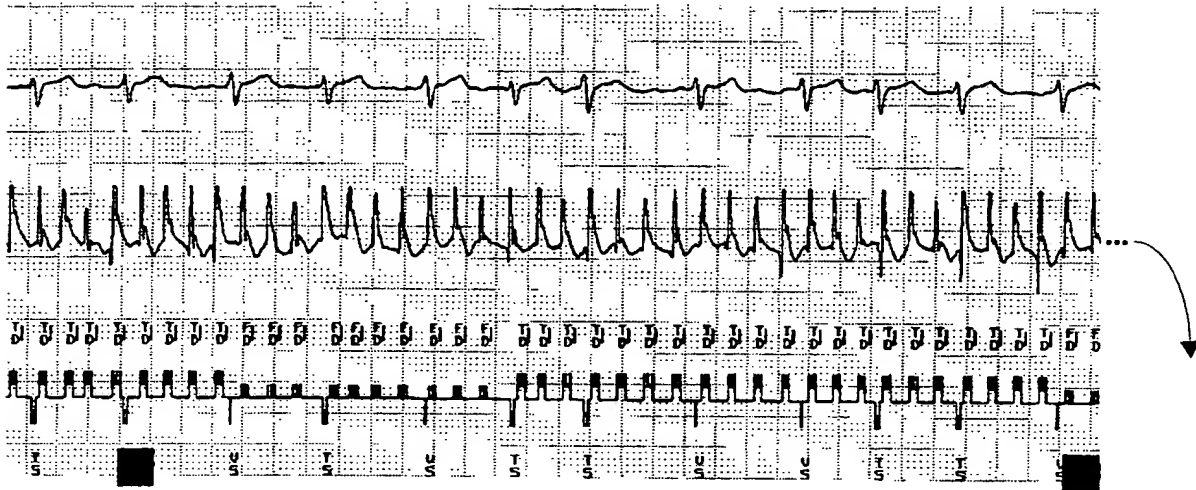
Figure 5-2. AF/AT Detection (Part 1)

Dual Chamber Atrial Tachyarrhythmia Detection

Atrial Tachycardia / Atrial Fibrillation (AF/AT) Detection

AF V_AT

AT V_AT



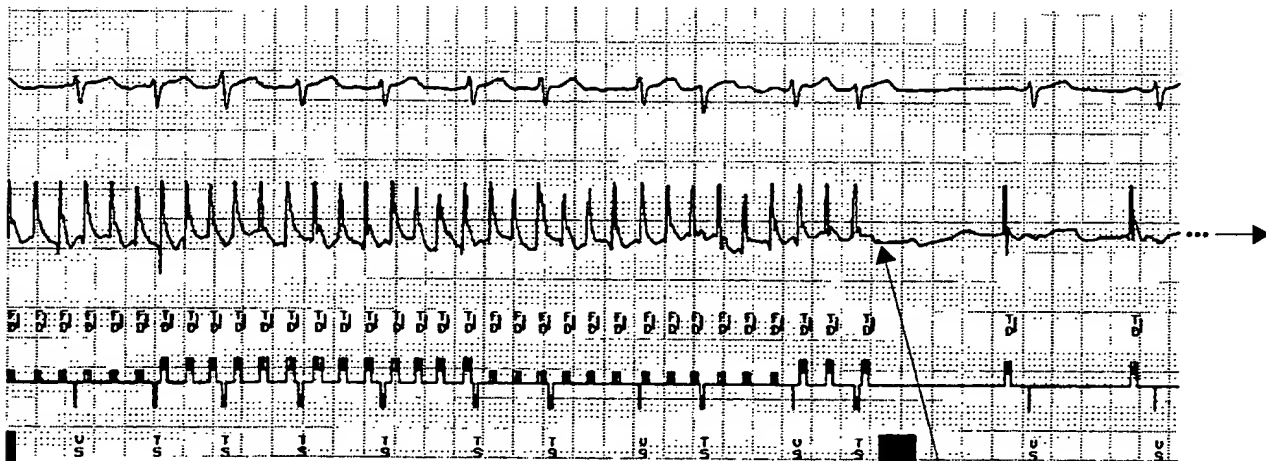
Sustained detection: atrial rhythm classification fluctuates between AF and AT.
AF/AT Dual Chamber VT/VF Detection criterion remains satisfied.

AF V_AT

AT V_AT

AF V_AT

AT V_AT



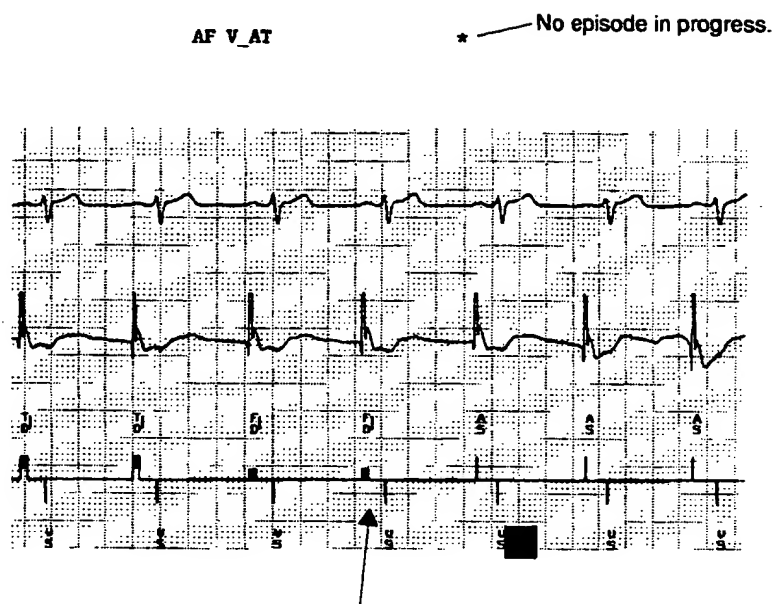
Sustained detection: atrial rhythm classification fluctuates between AF and AT.
AF/AT Dual Chamber VT/VF Detection criterion remains satisfied.

Atrial tachyarrhythmia spontaneously terminates
(78th ventricular event).

Figure 5-3. AF/AT Detection (Part 2)

Dual Chamber Atrial Tachyarrhythmia Detection

Atrial Tachycardia / Atrial Fibrillation (AF/AT) Detection



Atrial tachyarrhythmia episode termination detected (84th ventricular event).
See "AF/AT Episode Termination" on page 5-13.

Figure 5-4. AF/AT Detection (Part 3)

Non-Programmable Atrial Detection Criteria

The AMD uses several non-programmable criteria during atrial tachyarrhythmia detection to verify the presence of AT and AF (see also “Non-Programmable Ventricular Detection Criteria” on page 6-22). These criteria are based on analysis of cycle length and the *patterns* of atrial and ventricular activation (i.e., P:R relationships).

AF/AT Evidence Counter Criterion

The AF/AT Evidence Counter Criterion accumulates evidence of an atrial arrhythmia (i.e., A:V conduction is persistently greater than 1:1, and there is no evidence of far-field R-wave sensing).

On each ventricular event, the AMD adds one to the counter if P:R pattern information supports the presence of an atrial tachyarrhythmia. Otherwise, the AMD subtracts one from the counter, holds the value, or resets it to zero if it identifies sinus rhythm (see page 5-11).

The AF/AT Evidence Counter Criterion is satisfied when the AF/AT Evidence Count is greater than or equal to 32 (up to a maximum value of 47). Once the criterion is met, it will remain satisfied for as long as the AF/AT Evidence Count is greater than or equal to 27.

Far-Field R-Wave Criterion

If there are two atrial events in a ventricular interval, the AMD analyzes P:R pattern information to determine if one of the atrial events is actually a far-field R-wave.

The AMD identifies a sensed far-field R-wave if it detects **both**:

- a short-long pattern of P:P intervals, and
- either a short P:R interval (< 60 ms) or a short R:P interval (< 160 ms). See Figure 5-5.

The Far-Field R-Wave criterion is satisfied if at least 10 of the most recent 12 ventricular intervals have a far-field R-wave as identified above (i.e., *consistent* far-field R-wave sensing).

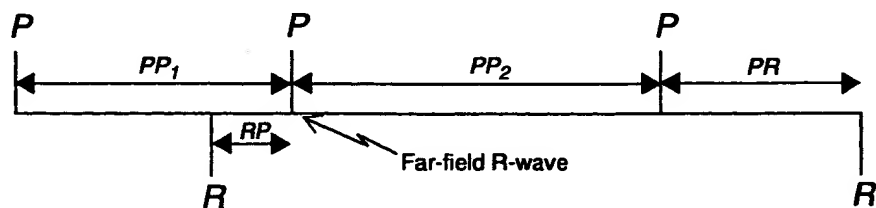


Figure 5-5. Intervals Used During Far-Field R-Wave Determination

Atrial Cycle Length Regularity Criterion

The AMD continuously monitors the atrial cycle length regularity to help discriminate between AF (irregular atrial cycle length) and AT (regular atrial cycle length).

Based on a set of the 12 most recent atrial intervals, the AMD considers the cycle length regular if the difference between the shortest and the longest atrial intervals is less than or equal to 25% of the median atrial cycle length.

A rhythm in the AF/AT overlap zone (see page 5-4) is classified as AT if the atrial cycle length was regular for at least 6 of the most recent 8 ventricular events. It is classified as AF if the atrial cycle length was regular for fewer than 6 of the most recent 8 ventricular events.

Sinus Rhythm Criterion

The Sinus Rhythm Criterion identifies normal sinus rhythm (or a paced rhythm) if 5 consecutive beats exhibit the P:R pattern of sinus rhythm (see Figure 6-5 on page 6-21). If this criterion is satisfied after preliminary detection of AF or AT, the AMD considers the episode terminated, and the AF/AT Evidence Counter resets to zero.

The AMD uses the Sinus Rhythm and Sinus Rhythm with Far-Field R-Wave criteria to increase the specificity of the AF/AT Evidence Counter.

Sinus Rhythm with Far-Field R-Wave Criterion

The Sinus Rhythm with Far-Field R-Wave criterion identifies sinus rhythm in the presence of far-field R-wave sensing. This criterion is similar to the Sinus Rhythm criterion, while also accounting for far-field R-wave sensing.

AF/AT Termination and Redetection

Outcome Monitoring

After delivering an automatic atrial therapy, the AMD resets the AF/AT Evidence Counter (page 5-9) and monitors the cardiac cycle length for three possible outcomes:

- Termination of the episode.
- Redetection of the original atrial tachyarrhythmia.
- Redetection of a different atrial tachyarrhythmia.

Note: After an atrial therapy delivery, if VF or VT is detected before either AF/AT redetection or AF/AT episode termination, all AF and AT therapies (automatic and patient-activated) are **disabled** until you re-enable them with the programmer.

Further automatic atrial therapies are not delivered unless the patient's cardiac rhythm fulfills the redetection requirements for an atrial tachyarrhythmia (page 5-14).

After delivery of atrial antitachycardia pacing therapy, outcome monitoring begins with the first cardiac cycle.¹ After atrial or ventricular high voltage therapy, outcome monitoring is delayed for one event, to compensate for the extended blanking period (520 ms) that follows high voltage therapy.

The sustained duration timer continues to run during AF/AT therapy and redetection. It resets to zero upon AT/AF episode termination.

1. To allow for additional time required by 50 Hz Burst pacing to terminate atrial tachyarrhythmias, AF and AT detection are temporarily suspended for 16 ventricular intervals after an automatic 50 Hz Burst therapy is delivered.

AF/AT Episode Termination

The AMD considers an AF or AT episode as terminated when **any** of the following conditions occurs:

- the AMD identifies sinus rhythm (i.e., 5 consecutive sinus beats) (see page 5-11),
- the rhythm has not been classified as either AF or AT for three minutes,
- the AMD detects VF or VT, or
- AF Detection is programmed OFF.

Once the AMD detects an atrial tachyarrhythmia, it considers the episode as ongoing until it detects episode termination. Any subsequent detection after termination marks the start of a new episode.

A rhythm that does not satisfy the termination definition is considered part of an ongoing episode. However, the next atrial therapy is not delivered unless the preliminary AF or AT detection criteria are fulfilled again.

If AF/AT episode termination is detected, the AF/AT Evidence Counter and the Sustained Duration Timer reset to zero.

AF/AT Redetection

AF/AT redetection occurs if the preliminary AF/AT detection criteria are met again after an atrial therapy is delivered (see “Preliminary AF/AT Detection” on page 5-4). If AF/AT episode duration exceeds the programmed duration required to initiate therapy (the sustained duration timer has been running since preliminary detection of the episode), the AMD can initiate the next programmed therapy for the current arrhythmia, and monitor for the outcome of that therapy once it is delivered.

Note: After an atrial therapy delivery, if VF or VT is detected before either AF/AT redetection or AF/AT episode termination, all AF and AT therapies (automatic and patient-activated) are disabled until you re-enable them with the programmer.

AF/AT Therapy Efficacy

A therapy is considered successful if arrhythmia termination occurs prior to any redetection. The therapy is considered unsuccessful if redetection occurs before termination.

If all of the programmed atrial therapies are unsuccessful, the AMD suspends them until either:

- the episode terminates,
- Detection is manually reset (i.e., you program Detection OFF, and then ON again) during the episode, or
- you reprogram any of the atrial therapies.

Dual Chamber Ventricular Tachyarrhythmia Detection

6

VF Detection 6-2

VT Detection 6-6

VT Stability Criterion 6-10

***Combined Count (VF and VT)
Detection 6-12***

VT/VF Discrimination 6-14

***Dual Chamber VT/VF Detection
Criteria 6-16***

***Non-Programmable Ventricular
Detection Criteria 6-22***

***VT/VF Termination and
Redetection 6-25***

VF Detection

The AMD detects VF as either a primary rhythm, or as part of a dual "VF + SVT" tachyarrhythmia.

If the AMD senses a programmed number of short R:R intervals, it detects a VF episode and delivers VF therapy. The AMD can be programmed to exclude rapidly conducted SVTs from VF Detection (page 6-16).

See page 6-4 for a more detailed description of VF Detection.

◆ **Programmable Parameters**

VF ENABLE	ON or OFF
V-Sensitivity (mV)*	Minimum level of electrical signal that registers as a sensed ventricular event.
INTERVAL (ms)	VFDI (VF Detection Interval): Cardiac cycle lengths shorter than the FDI are counted as VF events.
INITIAL NID	VF NID (VF Number of Intervals to Detect): Number of VF events the AMD must count to detect a VF episode.
REDETECT NID	VF RNID (VF Number of Intervals to Redetect): Number of VF events the AMD must count to redetect VF after a therapy.

* The programmed V-Sensitivity value applies to ventricular tachyarrhythmia detection and bradycardia pacing.

◆ **Programming Considerations**

To ensure VF detection backup, VF Detection cannot be OFF unless VT, AF, and AT Detection are all OFF.

To ensure proper VF detection, you should not program the VF Detection Interval below 300 ms.

Programming the ventricular sensitivity to 0.3 mV is recommended. See "Programming for Appropriate Sensing" on page 4-3.

The AMD can be programmed to exclude rapidly conducted SVTs from VF Detection - see "Dual Chamber VT/VF Detection Criteria" on page 6-16.

The AMD can be programmed to deliver one VT therapy attempt if the ventricular tachyarrhythmia cycle length is very regular - see "VT/VF Discrimination" on page 6-14.

The AMD features separately programmable NIDs for initial detection and redetection; it is thus possible to accelerate ventricular redetection by programming the Redetect NID lower than the Initial NID.

◆ **How to Program VF Detection**

1. From the **PARAMETERS** menu, select **DETECTION**.
2. Turn **VF ENABLE** ON and select VF Detection parameters.

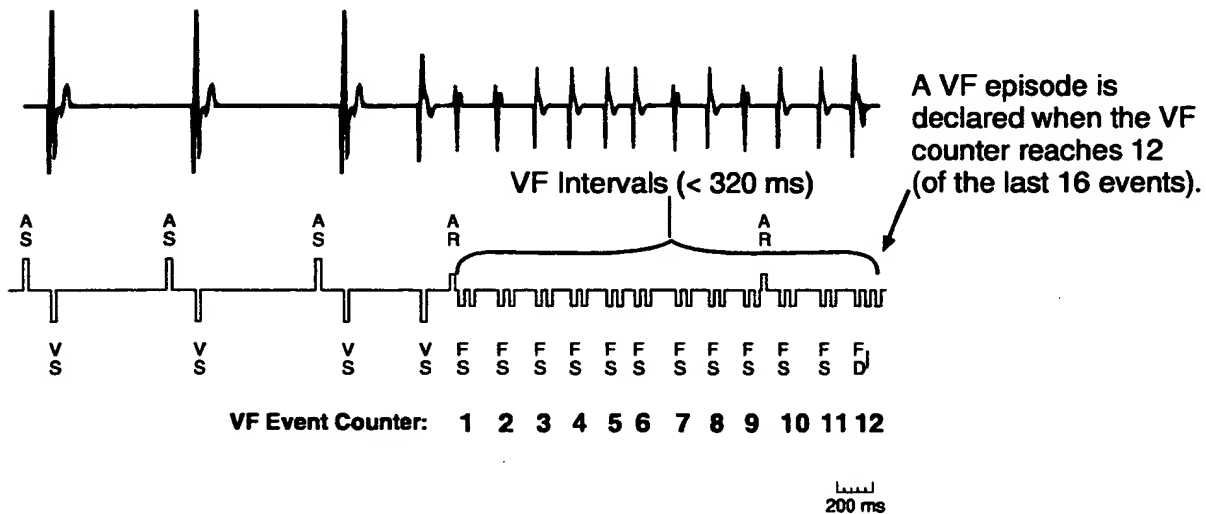
Programmable
VF Detection
Parameters
(circled)

DATA		TESTS		PARAMETERS		END SESSION		SPECIAL		PRINT	
DETECTION: Select parameters and then select PROGRAM.											
		ENABLE		ZONE RANGE		SHOW PRESENT					
AF	ON	100 ms	270 ms	<div style="display: flex; justify-content: space-between; align-items: center;"> <div style="border: 1px solid black; padding: 2px;">100</div> <div style="border: 1px solid black; padding: 2px;">270</div> </div> <div style="display: flex; justify-content: space-between; align-items: center;"> <div style="border: 1px solid black; padding: 2px;">170</div> <div style="border: 1px solid black; padding: 2px;">320</div> </div>							
AT	ON	170 ms	320 ms								
A Sensitivity(mV): 0.3											
		ENABLE		INITIAL REDETECT		INTERVAL					
VF	ON	18/24	18/24	320 ms	<div style="display: flex; justify-content: space-between; align-items: center;"> <div style="border: 1px solid black; padding: 2px;">120</div> <div style="border: 1px solid black; padding: 2px;">320</div> </div> <div style="display: flex; justify-content: space-between; align-items: center;"> <div style="border: 1px solid black; padding: 2px;">120</div> <div style="border: 1px solid black; padding: 2px;">400</div> </div>						
VT	ON	12	16	400 ms							
Dual Chamber VT/VF Detection Criteria: AF/AT, Sinus Tach, Other 1:1 SVTs											
V Sensitivity(mV): (0.3) VT Stability(ms): 50 VT/VF Discrim: ON											

◆ **How VF Detection Works**

VF Interval Criterion – If none of the dual chamber detection criteria (page 6-16) nor VT/VF Discrimination (page 6-14) is enabled, the AMD detects ventricular fibrillation by applying the VF Interval Criterion:

When the patient's ventricular cycle length is shorter than the VF_{DI}, the AMD marks that event as a VF event. Each sensed VF event registers on the VF event counter in the AMD memory. If the VF event counter reaches the VF Initial NID (Figure 6-1), the AMD detects a VF episode and delivers the first programmed VF therapy. After the therapy, if the VF event counter reaches the VF Redetect NID, the AMD redetects VF and delivers the next programmed VF therapy. (See also "Combined Count (VF and VT) Detection" on page 6-12.)



	<u>ENABLE</u>	<u>INITIAL</u>	<u>REDETECT</u>	<u>INTERVAL</u>
VF	ON	12/16	9/12	320 ms
VT	ON	12	8	400 ms

Dual Chamber VT/VF Detection Criteria: ALL OFF

V Sensitivity (mV): 0.3

Figure 6-1. VF Detection

The VF NIDs are defined as a number of VF events within a “VF detection window.” For example, given a VF NID of 12/16, the AMD detects a VF episode when any twelve of the most recent sixteen cardiac cycles were VF events. All the VF NID values are 75% of the detection window: 12/16; 18/24; 24/32; etc.

“VF + SVT” Dual Tachyarrhythmia Detection – If any of the dual chamber detection criteria are enabled (see page 6-16), the AMD automatically monitors for VF as part of a dual tachyarrhythmia. The AMD delivers VF therapy if all of the following conditions are satisfied:

- VF detection is fulfilled via the Interval or Combined Count criterion,
- the programmed SVT Minimum Interval \leq median R-R interval,
- there is evidence of an atrial tachyarrhythmia (i.e., A:V conduction is greater than 1:1, excluding far-field R-wave sensing – see page 6-22), and
- there is A:V dissociation (see page 6-23).

A “VF + SVT” episode is treated with the programmed VF therapy(ies). Redetection, if necessary, occurs according to the single chamber VF Redetection criteria (i.e., VF redetection is fulfilled via the Interval or Combined Count criterion).

VT Detection

The AMD detects VT as either a primary rhythm, or as part of a dual "VT+ SVT" tachyarrhythmia.

If the AMD senses the programmed number of VT intervals, the AMD detects a VT episode and delivers VT therapy. The AMD can be programmed to exclude rapidly conducted SVTs from VT Detection (page 6-16).

See page 6-8 for a more detailed description of VT Detection.

◆ **Programmable Parameters**

VT ENABLE	ON or OFF.
V-Sensitivity (mV)*	Minimum level of electrical signal that registers as a sensed ventricular event.
INTERVAL (ms)	VTDI (Ventricular Tachycardia Detection Interval): Cardiac cycle lengths shorter than VTDI and longer than VFDI (see page 6-2) are counted as VT events.
INITIAL NID	VT NID (Number of Intervals to Detect): Number of VT events the AMD must count to detect a VT episode.
REDETECT NID	VT RNID (Number of Intervals to Redetect): Number of VT events the AMD must count to redetect VT after a therapy.

* The programmed V-Sensitivity value applies to tachyarrhythmia detection and bradycardia pacing.

◆ **Programming Considerations**

To ensure VF detection backup during VT episodes, VT Detection cannot be ON unless VF Detection is also ON.

To ensure proper VT detection, program the Ventricular Tachycardia Detection Interval (VTDI) to a value that is at least 40 ms longer than the patient's tachycardia cycle length.

Programming the ventricular sensitivity to 0.3 mV is recommended. See "Programming for Appropriate Sensing" on page 4-3.

The AMD can be programmed to exclude rapidly conducted SVTs from VT Detection - see "Dual Chamber VT/VF Detection Criteria" on page 6-16.

The AMD features separately programmable NIDs for initial detection and redetection; it is thus possible to accelerate ventricular redetection by programming the Redetect NID lower than the Initial NID.

◆ **How to Program VT Detection**

1. From the **PARAMETERS** menu, select **DETECTION** (partial screen shown below).
2. Turn **VT ENABLE** ON, and select VT Detection parameters.

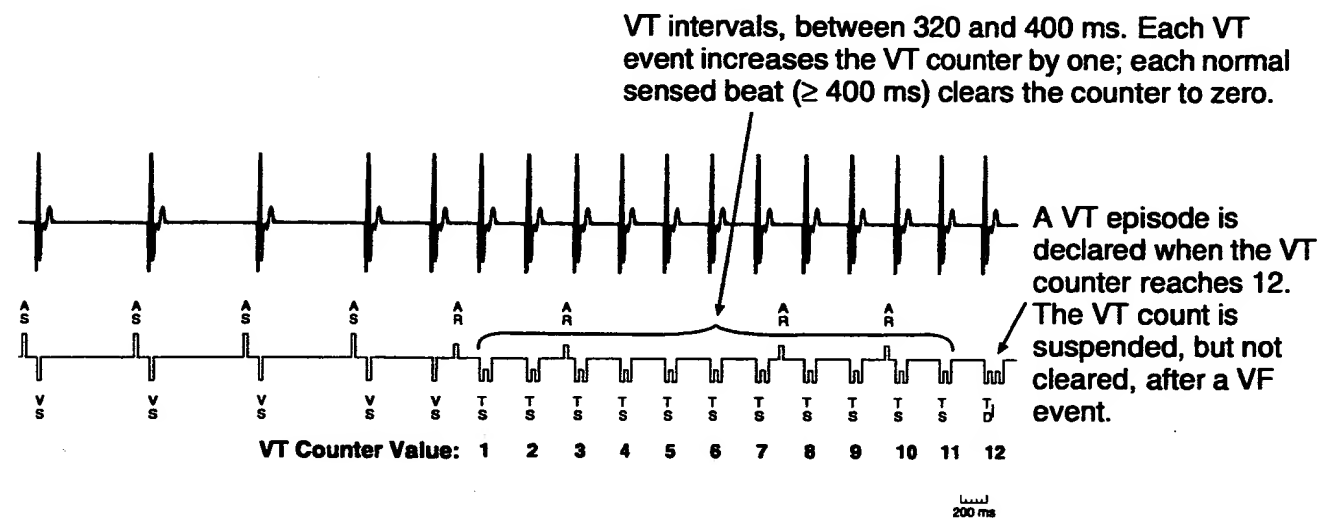
Programmable
VT Detection
Parameters
(circled)

DATA		TESTS		PARAMETERS		END SESSION		SPECIAL		PRINT	
DETECTION: Select parameters and then select PROGRAM.											
		ENABLE		ZONE RANGE		SHOW PRESENT					
AF	ON	188 ms	278 ms	<div style="border: 1px solid black; padding: 5px; text-align: center;"> 188 ██████████ 278 178 ██████████ 328 </div>							
AT	ON	178 ms	328 ms								
A Sensitivity(mV): 0.3											
		ENABLE		INITIAL		REDETECT		INTERVAL			
VF	ON	18/24	18/24	328 ms	<div style="border: 1px solid black; padding: 5px; text-align: center;"> 128 ██████████ 328 128 ██████████ 488 </div>						
VT	ON	12	16	488 ms							
Dual Chamber VT/VF Detection Criteria: AF/AT, Sinus Tach, Other 1:1 SUTs											
V Sensitivity(mV): (0.3) VT Stability(ms): 50 VT/VF Discrim: ON											

◆ **How VT Detection Works**

VT Interval Criterion – If none of the Dual Chamber Detection criteria is enabled, the AMD detects sustained ventricular tachycardias by applying the VT Interval Criterion:

When the ventricular cycle length falls within the VT detection zone, the AMD applies the optional VT Stability criterion (page 6-10), if it is enabled. If the VT Stability criterion is also met, the AMD marks that cycle as a VT event and increments the VT event counter. If the VT event counter reaches the VT Initial NID, the AMD detects a VT episode and delivers the first programmed VT therapy. After the therapy, if the VT event counter reaches the VT Redetect NID, the AMD redetects VT and delivers the next programmed VT therapy. (See also “Combined Count (VF and VT) Detection” on page 6-12.)



	ENABLE	INITIAL	REDETECT	INTERVAL
VF	ON	12/16	9/12	320 ms
VT	ON	12	8	400 ms

Dual Chamber VT/VF Detection Criteria: ALL OFF
V Sensitivity (mV): 0.3

Figure 6-2. VT Detection

The VT event counter counts only consecutive VT events. The event counter resets to zero whenever an interval fails the Interval or Stability Criterion. The VT counter is suspended at its current value, not reset, if an interval falls in the VF zone.

“VT + SVT” Dual Tachyarrhythmia Detection – If any of the dual chamber detection criteria is enabled (see page 6-16), the AMD automatically monitors for VT as part of a dual tachyarrhythmia, and delivers VT therapy if all of the following conditions are satisfied:

- VT detection is fulfilled via the Interval or Combined Count criterion,
- the programmed SVT Minimum Interval \leq median R-R interval,
- there is evidence of an atrial tachyarrhythmia (i.e., A:V conduction is greater than 1:1, excluding far-field R-wave sensing – see page 6-22),
- there is A:V dissociation (see page 6-23), and
- the ventricular cycle length is regular (see page 6-24).

A “VT + SVT” episode is treated with the programmed VT therapy(ies). Redetection, if necessary, occurs according to the single chamber VT Redetection criteria (i.e., VT redetection is fulfilled via the Interval or Combined Count criterion).

VT Stability Criterion

The VT Stability Criterion is an optional VT Detection feature that rejects rapid ventricular rhythms (in the VT detection zone) with irregular intervals.

◆ Programmable Parameters

VT Stability (ms)	Maximum acceptable variation among measured cycle lengths, or OFF.
-------------------	--

◆ Programming Considerations

Choosing a small VT Stability Interval value (e.g., 30 ms) may not allow for normal variation in a VT cycle length. Therefore, a smaller VT Stability Interval could decrease the sensitivity of the ventricular detection algorithm to detect VT.

The VT Stability Criterion compares measured cycle lengths that have been truncated to multiples of 10 ms, permitting a rounding error of approximately +10 ms from the programmed VT Stability value.

◆ How to Program VT Stability

1. From the **PARAMETERS** menu, select **DETECTION**.
2. Select a VT Stability (ms) value.

Programmable
VT Stability
Parameter
(circled)

DATA		TESTS		PARAMETERS		END SESSION		SPECIAL		PRINT	
DETECTION: Select parameters and then select PROGRAM.											
		ENABLE		ZONE RANGE		SHOW PRESENT					
AF	ON	100 ms	270 ms	100 270							
AT	ON	170 ms	320 ms	170 320							
A Sensitivity(mV): 0.3											
		ENABLE		INITIAL		REDETECT		INTERVAL			
VF	ON	18/24	18/24	320 ms		120 320					
VT	ON	12	16	400 ms		400					
Dual Chamber VT/VF Detection Criteria: AF/AT, Sinus Tach, Other 1:1 SUTs											
V Sensitivity(mV): 0.3 VT Stability(ms): 50 VT/VF Discrim: ON											

Dual Chamber Ventricular Tachyarrhythmia Detection

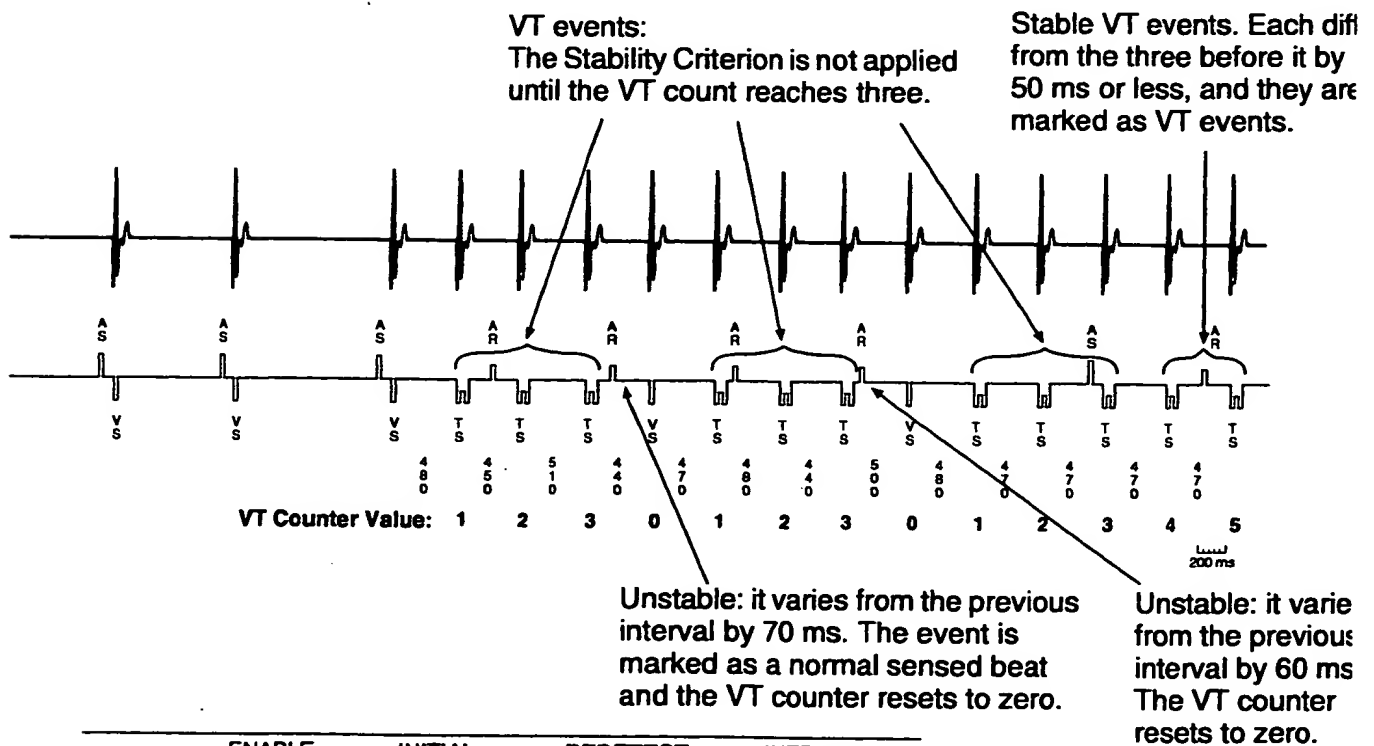
VT Stability Criterion

◆ How the VT Stability Criterion Works

When the VT Stability Criterion is enabled, an interval in the VT zone is considered "unstable" if the difference between it and any of the three previous intervals is greater than or equal to the programmed Stability Interval value (Figure 6-3).

The AMD does not apply the VT Stability Criterion until the VT event count reaches three. When an interval in the VT zone fails to meet the VT Stability Criterion, it is marked as a normal sensed event and the VT event count resets to zero.

The VT Stability Criterion must be re-satisfied during redetection if it is enabled.



	<u>ENABLE</u>	<u>INITIAL</u>	<u>REDETECT</u>	<u>INTERVAL</u>
VF	ON	12/16	9/12	320 ms
VT	ON	12	8	400 ms

Dual Chamber VT/VF Detection Criteria: ALL OFF

V Sensitivity (mV): 0.3 VT Stability (ms): 50 VT/VF Discrim: OFF

Figure 6-3. VT Stability Criterion

Combined Count (VF and VT) Detection

Combined Count detection helps the AMD promptly detect or redetect a ventricular tachyarrhythmia when the cycle length is fluctuating between the VF and VT zones.

The AMD tracks the combined number of events registered on the VF and VT counters, and if this sum reaches the Combined Number of Intervals to (Re)Detect, VF or VT is (re)detected.

◆ **Programmable Parameters**

Combined Count detection is automatic (not programmable) when VT Detection is enabled, and cannot be disabled.

The AMD can be programmed to exclude rapidly conducted SVTs from Combined Count detection - see page 6-16.

◆ **How Combined Count Detection Works**

Combined Count detection is automatically enabled when the VF event counter reaches six. It applies a Combined Number of Intervals to Detect (CNID):

Initial CNID = VF Initial NID \times 7/6, rounded down.

Redetect CNID = VF Redetect NID \times 7/6, rounded down.

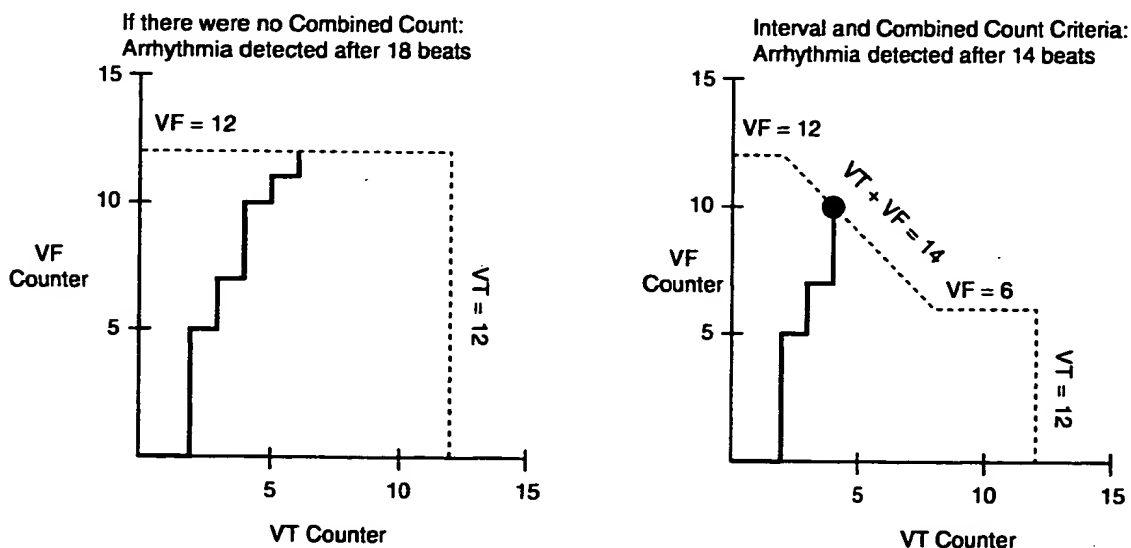
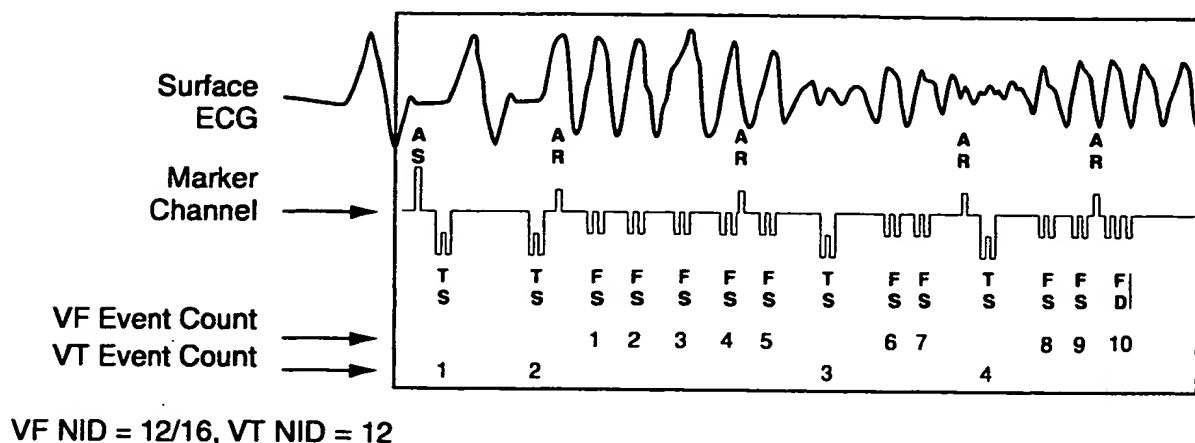
For example, when the VF Initial NID is programmed to 18, the Initial CNID is 21; when the VF Redetect NID is 12, the Redetect CNID is 14.

Combined Count (re)detection is fulfilled when the sum of the VF and VT event counters equals or exceeds the CNID (Figure 6-4). The AMD then reviews the eight intervals preceding (re)detection:

- If any of the eight was in the VF zone, the episode is classified as VF.
- If all eight were outside the VF zone, the episode is classified as VT.

Dual Chamber Ventricular Tachyarrhythmia Detection

Combined Count (VF and VT) Detection



A graph of the event counters during a monitored ventricular tachyarrhythmia episode shows how the Combined Count Criterion helps ensure prompt detection when the ventricular cycle length varies between VF and VT detection zones.

Figure 6-4. Combined Count Detection (Example of VF)

VT/VF Discrimination

VT/VF Discrimination is an optional feature that attempts one VT therapy for a rapid, regular ventricular arrhythmia detected in the VF zone.

See page 6-15 for a more detailed description of VT/VF Discrimination.

◆ **Programmable Parameters**

VT/VF Discrim:	ON or OFF.
-----------------------	-------------------

◆ **Programming Considerations**

VT/VF Discrimination is not applied unless both VF and VT Detection are enabled.

The choice to use VT/VF Discrimination depends upon the patient's VF and VT cycle lengths. Only if the patient exhibits a clinical VT whose cycle length falls within the VF detection zone should VT/VF Discrimination be programmed ON.

Dual Chamber Ventricular Tachyarrhythmia Detection VT/VF Discrimination

◆ How to Program VT/VF Discrimination

1. From the **PARAMETERS** menu, select **DETECTION**.
2. Turn VT/VF Discrim: ON.

Programmable
VT/VF Discrimination
Parameter
(circled)

DATA		TESTS		PARAMETERS		END SESSION		SPECIAL		PRINT	
DETECTION: Select parameters and then select PROGRAM.											
		ENABLE		ZONE RANGE		SHOW PRESENT					
AF	ON	100 ms	270 ms	<div style="border: 1px solid black; padding: 5px; display: inline-block;"> 100 ██████████ 270 170 ██████████ 320 </div>							
AT	ON	170 ms	320 ms								
A Sensitivity(mV): 0.3											
		ENABLE		INITIAL		REDETECT		INTERVAL		<div style="border: 1px solid black; padding: 5px; display: inline-block;"> 120 ██████████ 320 120 ██████████ 400 </div>	
VF	ON	10/24	10/24	320 ms							
VT	ON	12	16	400 ms							
Dual Chamber VT/VF Detection Criteria: AF/AT, Sinus Tach, Other 1:1 SVTs											
V Sensitivity(mV): 0.3 VT Stability(ms): 50 VT/VF Discrim: ON											

◆ How VT/VF Discrimination Works

The VT/VF Discrimination feature is applied only during initial detection. It initiates only one scan of the first VT therapy (i.e., a single antitachycardia pacing sequence or one non-committed cardioversion shock). If this attempt fails to terminate or decelerate the episode, the arrhythmia will be redetected as VF and treated with the first programmed VF therapy.

If VT/VF Discrimination is ON, a rapid, regular ventricular arrhythmia is detected as VT and treated with the first programmed scan of VT therapy if all of the following conditions are satisfied:

- the ventricular cycle length is regular (page 6-24), and
- VF detection is fulfilled via the Interval or Combined Count criterion, and
- the R:R median is at least 240 ms.

A detected "VF + SVT" dual tachyarrhythmia always receives VF therapy regardless of VT/VF Discrimination.

Dual Chamber VT/VF Detection Criteria

The AMD provides three optional Dual Chamber VT/VF Detection Criteria that withhold inappropriate VT and VF detection during rapidly conducted supraventricular tachycardias (SVTs) that might satisfy the ventricular rate criteria alone.

Dual chamber VT/VF detection combines P:R pattern information with both atrial and ventricular rate measurements to classify ventricular arrhythmias more specifically.

◆ **Programmable Parameters**

AF/AT	Withholds ventricular detection for atrial fibrillation, atrial flutter, and atrial tachycardia (see page 6-19).
Sinus Tachycardia	Withholds ventricular detection for sinus tachycardia (see page 6-20).
Other 1:1 SVTs	Withholds ventricular detection for AVNRT and other 1:1 SVTs (see page 6-20).
SVT Minimum Interval	The ventricular cycle length must be greater than this value for ventricular detection to be withheld.

◆ **Programming Considerations**

If Dual Chamber VT/VF Detection is not enabled, a rapidly conducted SVT could be detected as VF or VT.

To ensure reliable ventricular detection, dual tachyarrhythmia detection is automatically enabled when any Dual Chamber VT/VF Detection criterion is enabled.

Caution should be used when programming the Sinus Tachycardia and the Other 1:1 SVTs criteria in patients who exhibit 1:1 retrograde conduction.

Dual Chamber Ventricular Tachyarrhythmia Detection

Dual Chamber VT/VF Detection Criteria

◆ How to Program the Dual Chamber VT/VF Detection Criteria

1. From the **PARAMETERS** menu, select **DETECTION** (partial screens shown below.)
2. Enable the Dual Chamber VT/VF Detection Criteria as desired, and select an SVT Minimum Interval.

Programmable
Dual Chamber VT/VF Detection
Parameters
(circled)

Touching screen in this area
brings up the Dual Chamber
VT/VF Detection Criteria
pop-up menu

DATA		TESTS		PARAMETERS		END SESSION		SPECIAL		PRINT	
DETECTION: Select parameters and then select PROGRAM.											
		ENABLE		ZONE RANGE		SHOW PRESENT					
AF	ON	180 ms	270 ms	<div style="display: flex; justify-content: space-between;"> <div>100 <div style="width: 100%; height: 10px; background: linear-gradient(to right, black 40%, white 40%);"></div> 270</div> <div>170 <div style="width: 100%; height: 10px; background: linear-gradient(to right, black 40%, white 40%);"></div> 320</div> </div>							
AT	ON	170 ms	320 ms								
A Sensitivity(mV): 0.3											
		ENABLE		INITIAL		REDETECT		INTERVAL			
VF	ON	18/24	18/24	320 ms	<div style="display: flex; justify-content: space-between;"> <div>120 <div style="width: 100%; height: 10px; background: linear-gradient(to right, black 40%, white 40%);"></div> 320</div> <div>400 <div style="width: 100%; height: 10px; background: linear-gradient(to right, black 40%, white 40%);"></div> 400</div> </div>						
VT	ON	12	16	400 ms							
Dual Chamber VT/VF Detection Criteria: AF/AT, Sinus Tach, Other 1:1 SUTs											
V Sensitivity(mV): 0.3 VT Stability(ms): 50 VT/VF Discrim: ON											

DATA		TESTS		PARAMETERS		END SESSION		SPECIAL		PRINT	
DETECTION: Select parameters and then select PROGRAM.											
DUAL CHAMBER VT/VF DETECTION CRITERIA											
If programmed ON, VT/VF therapy is withheld in the presence of rapidly conducting:											
AF/AT:						ON					
Sinus Tach:						ON					
Other 1:1 SUTs:						ON					
only if the RR interval > SUT Minimum Interval: 320											
CLOSE											

◆ **How the Dual Chamber VT/VF Detection Criteria Work**

When an SVT is rapidly conducted to the ventricles and neither "VF + SVT" nor "VT + SVT" detection occurs, the rhythm is evaluated under the programmed dual chamber VT/VF detection criteria:

- AF/AT (page 6-19)
- Sinus Tachycardia (page 6-20)
- Other 1:1 SVTs (page 6-20)

If the rhythm fulfills any of the programmed Dual Chamber VT/VF Detection criteria, the AMD withholds ventricular detection, and continues to monitor for possible atrial detection and therapy (see "Dual Chamber Atrial Tachyarrhythmia Detection" on page 5-1).

The dual chamber VT/VF detection criteria are applied only on initial detection, and only if VF Detection is enabled.

Dual Tachyarrhythmia Detection – To ensure VF and VT detection and therapy when *both* a ventricular tachyarrhythmia and an SVT are present, dual tachyarrhythmia detection is automatically enabled when any dual chamber VT/VF detection criterion is enabled (see page 6-5 and page 6-9).

SVT Minimum Interval – To avoid inappropriately withholding therapy for VT or VF, the Dual Chamber VT/VF Detection criteria are rate limited by the SVT Minimum Interval. If the R:R median is less than the SVT Minimum Interval value, the Dual Chamber VT/VF Detection Criteria do not classify the rhythm as an SVT.

AF/AT Dual Chamber VT/VF Detection Criterion

The AF/AT Dual Chamber VT/VF Detection Criterion (AF/AT Criterion) prevents VF or VT detection during an AF or AT episode that is rapidly conducted to the ventricles.

The AF/AT Criterion consists of two independent rules: the atrial fibrillation rule and the atrial flutter rule. If either rule is satisfied, the AF/AT Criterion is satisfied and the rhythm does not receive ventricular therapy.

Atrial Fibrillation Rule

The Atrial Fibrillation Rule is satisfied if:

- A:V conduction is greater than 1:1 (see page 6-22), without cumulative evidence of far-field R-wave sensing (see page 6-23),
- the P:P median is 94% or less of the R:R median, and
- the ventricular cycle length is irregular (see page 6-24).

Atrial Flutter Rule

The Atrial Flutter Rule is satisfied if:

- P:R pattern information indicates a 2:1 atrial flutter, without cumulative evidence of far-field R-wave sensing (see page 6-23), and
- there is A:V association (see page 6-23).

Sinus Tachycardia Dual Chamber VT/VF Detection Criterion

The Sinus Tachycardia Dual Chamber VT/VF Detection Criterion (ST Criterion) prevents VF or VT detection during a sinus tachycardia that is rapidly conducted to the ventricles. If the ST Criterion is satisfied, the rhythm does not receive ventricular therapy.

The ST Criterion is satisfied if:

- P:R pattern information indicates a 1:1 sinus tachycardia (i.e., a 1:1 rhythm with atrial events occurring in Zone 3; see Figure 6-5), without cumulative evidence of far-field R-wave sensing (see page 6-23).

Other 1:1 SVT Dual Chamber VT/VF Detection Criterion

The Other 1:1 SVT Dual Chamber VT/VF Detection Criterion (Other 1:1 SVT Criterion) withholds VF or VT detection during a rapidly conducted 1:1 SVT in which the atria and ventricles are activated at approximately the same time (e.g., AV Nodal Reentry Tachycardia). If the Other 1:1 SVT Criterion is satisfied, the rhythm does not receive ventricular therapy.

The Other 1:1 SVT Criterion is satisfied if:

- P:R pattern information indicates a 1:1 SVT with atrial events occurring in Zones 1 or 4; see Figure 6-5.

Dual Chamber Ventricular Tachyarrhythmia Detection

Dual Chamber VT/VF Detection Criteria

Figure 6-5 defines the zones used during P:R analysis of 1:1 SVTs, and the atrial events that are expected in each zone.

Zone Expected Atrial Events Due To:

- 1 Junctional rhythms, PACs, PVCs, atrial fibrillation, atrial flutter (P_1)
- 2 Retrograde conduction (P_2)
- 3 Normal conduction (sinus rhythm, sinus tachycardia) (P_3)
- 4 Junctional rhythms, PACs, PVCs, atrial fibrillation, atrial flutter (P_4)

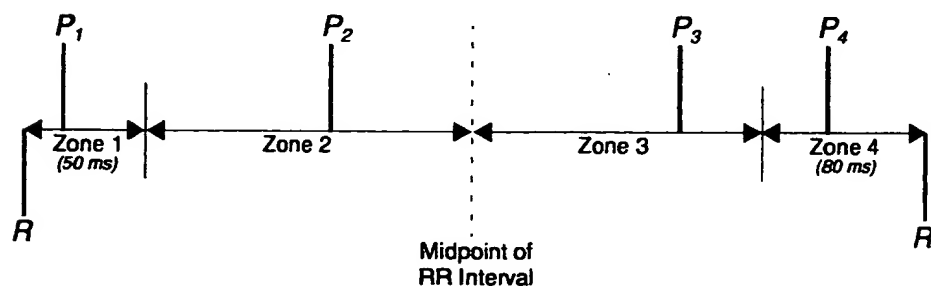


Figure 6-5. Zones Used During P:R Pattern Analysis

Non-Programmable Ventricular Detection Criteria

The AMD uses several non-programmable criteria during ventricular tachyarrhythmia detection (see also "Non-Programmable Atrial Detection Criteria" on page 5-9). These criteria are based on analysis of cycle length and the *patterns* of atrial and ventricular activation (i.e., P:R relationships).

AF* Evidence Counter Criterion

The AMD uses an AF* Evidence Counter Criterion during Dual Chamber VT/VF Detection to withhold VF or VT detection during atrial fibrillation, and to support detection of a dual tachyarrhythmia.¹

On each ventricular event, the AMD adds one to the AF* counter if the P:R pattern information supports the presence of a stable atrial tachyarrhythmia. If the P:R pattern is inconclusive, inconsistent, or if far-field R-wave sensing is detected, the AF* counter is left unchanged. If there was no atrial event during the current R:R cycle, the AMD subtracts one from the counter.

The AF* Evidence Counter Criterion is satisfied when the AF* Evidence Count is greater than or equal to 6 (up to a maximum value of 10). Once the criterion is met, it remains satisfied for as long as the AF* Evidence Count is greater than or equal to 5.

1. The AF* Evidence Counter Criterion is also used during Mode Switch operation to initiate DDD ↔ DDI switches (see page 4-14).

Far-Field R-Wave Criterion

If there are two atrial events in a ventricular interval, the AMD analyzes P:R pattern information to determine if one of the atrial events is actually a far-field R-wave.

The AMD identifies a sensed far-field R-wave if it detects **both**:

- a short-long pattern of P:P intervals, and
- either a short P:R interval (< 60 ms) or a short R:P interval (< 160 ms).

The Far-Field R-Wave criterion is satisfied if at least 10 of the most recent 12 ventricular intervals have a far-field R-wave as identified above (i.e., *consistent* far-field R-wave sensing).

See Figure 5-5 on page 5-10.

A:V Dissociation Criterion

The A:V Dissociation Count criterion provides cumulative evidence that sensed atrial events are dissociated from ventricular events. The AMD uses this criterion to help identify a dual tachyarrhythmia.

The AMD considers a rhythm to be A:V dissociated if at least 4 of the most recent 8 ventricular intervals exhibit **either**:

- no atrial events in the ventricular interval, or
- a P:R interval that differs from the average of the previous eight P:R intervals by more than 40 ms.

Ventricular Cycle Length Regularity Count

The AMD continuously measures the regularity of the ventricular cycle length to refine its dual-chamber detection capabilities. The **ventricular regularity count** is a percentage total of the two most commonly occurring intervals (of at least 240 ms), among the last 18 ventricular intervals. For example, suppose that the last 18 R:R intervals were:

340, 330, 320, 330, 330, 330, 340, 330, 330, 340, 340, 340, 340, 340, 340, 340, 330, 340, and 340.

In this example, the regularity count is 95% (i.e., 17/18). The most commonly occurring intervals are 340 ms (ten intervals) and 330 ms (seven intervals), for a total of 17/18.

- To qualify for the VT/VF Discrimination feature, the regularity count must be at least 75%.
- For a "VT + SVT" dual tachyarrhythmia to be detected, the regularity count must be at least 75%.
- To withhold VF/VT detection under the Atrial Fibrillation rule (page 6-19), the regularity count must be 50% or less.

VT/VF Termination and Redetection

Outcome Monitoring

After delivering an automatic therapy, the AMD monitors the cardiac cycle length for three possible outcomes:¹

- Termination of the episode.
- Redetection of the original ventricular tachyarrhythmia.
- Redetection of a different ventricular arrhythmia, including VT Acceleration.

Further automatic ventricular therapies are not delivered unless the patient's cardiac rhythm fulfills the redetection requirements a ventricular tachyarrhythmia.

The Dual Chamber VT/VF Detection Criteria are not applied during redetection. VT/VF Discrimination is also not applied during redetection. However, the VT Stability Criterion must be re-satisfied continually if it is enabled.

◆ Programming Considerations

The AMD features separately programmable VF and VT NIDs for initial detection and redetection; it is thus possible to accelerate ventricular arrhythmia redetection by programming Redetect NIDs lower than the Initial NIDs. Both the VF RNID and the VT RNID take effect during any type of ventricular arrhythmia episode.

1. VT Detection is temporarily suspended for 17 events, paced or sensed, following ventricular defibrillation therapy.

VT and VF Episode Termination

A VT or VF episode is considered successfully terminated when eight consecutive R:R intervals are greater than or equal to the VT detection interval¹ (Figure 6-6). Once the AMD detects an arrhythmia, it considers the episode as ongoing until it detects termination. Any subsequent detection after termination marks the start of a new episode.

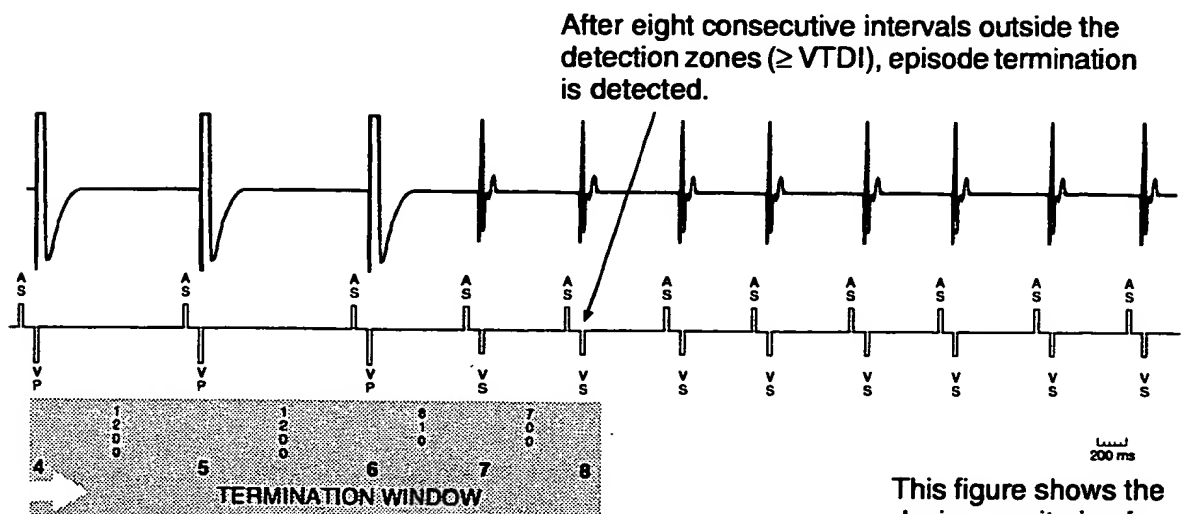
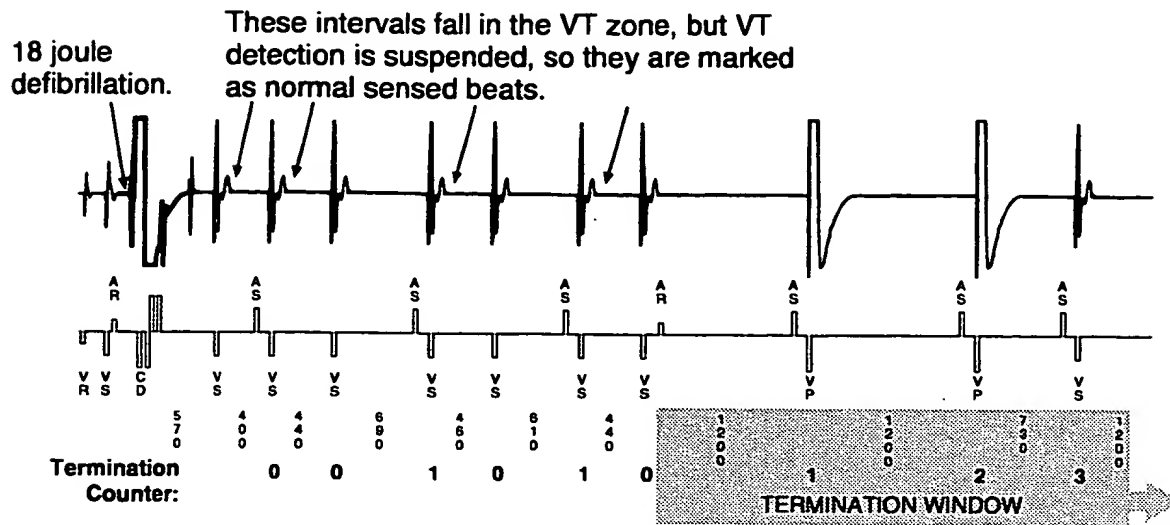
A ventricular rhythm that does not satisfy the termination definition is considered part of an ongoing episode. However, the next ventricular therapy is not delivered unless the programmed redetection criteria are fulfilled.

After ventricular antitachycardia pacing therapy, the counter for episode termination begins with the first ventricular cycle. After cardioversion or defibrillation, the counter for episode termination begins with the second ventricular event following the shock. (Due to the extended post shock blanking, this event may be the *third* event on the electrogram.)

1. VF Detection Interval when VT Detection is programmed OFF.

Dual Chamber Ventricular Tachyarrhythmia Detection

VT/VF Termination and Redetection



This figure shows the device monitoring for episode termination after VF therapy. Although VT detection is suspended after the therapy, intervals in the VT zone do reset the termination counter.

This defibrillation therapy is designated as "successful," because termination occurs before any redetection.

	ENABLE	INITIAL	REDETECT	INTERVAL
VF	ON	12/16	9/12	320 ms
VT	ON	12	8	400 ms

VF THERAPY:	1	2	3	4	5	6
THERAPY STATUS:	ON	ON	ON	ON	ON	ON
ENERGY (J):	18	27	27	27	27	27

Figure 6-6. Termination of VF After Therapy

Ventricular Redetection

Redetection occurs if the VF or VT event counter reaches its Redetect NID, or if the combined VF and VT event counters reach the Redetect CNID (see page 6-12). The AMD then delivers the next programmed therapy for the current arrhythmia, and resumes monitoring for the outcome of that therapy.

If VF or an accelerated VT is redetected after the delivery of an antitachycardia pacing sequence, the AMD skips the subsequent sequences of the pacing therapy for the duration of this episode and proceeds to deliver the next therapy programmed for the current arrhythmia.

Figure 6-7 illustrates redetection of VT after cardioversion therapy.

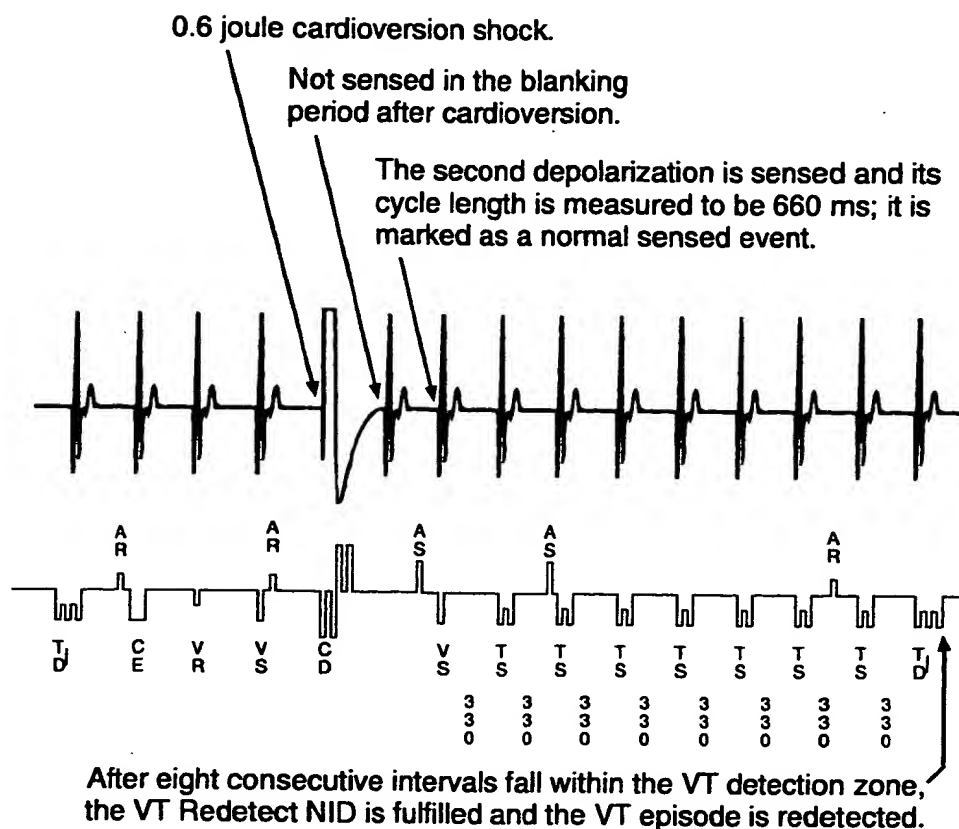
VT Acceleration

VT is classified as accelerated when it is redetected during a VT episode and [the average of the four intervals before redetection] has decreased by 60 ms or more, compared to [the average of the four intervals before the initial VT detection¹]. The current redetection becomes the “most recent accelerated redetection” used to evaluate future VT accelerations under the 60 ms rule above.

If VT Acceleration occurs after the delivery of an antitachycardia pacing sequence, the AMD skips the subsequent sequences of the pacing therapy for the duration of this episode and delivers the next programmed VT therapy.

1. Or before the most recent “accelerated” VT redetection.

Dual Chamber Ventricular Tachyarrhythmia Detection VT/VF Termination and Redetection



200 ms

	<u>ENABLE</u>	<u>INITIAL</u>	<u>REDETECT</u>	<u>INTERVAL</u>		
VF	ON	12/16	9/12	320 ms		
VT	ON	12	8	400 ms		

VT THERAPY:	1	2	3	4	5	6
THERAPY STATUS:	ON	ON	ON	ON	ON	ON
THERAPY TYPE:	CV	CV	CV	CV	CV	CV
ENERGY (J):	0.6	10	27	27	27	27

This therapy was unsuccessful: a ventricular tachyarrhythmia was redetected before episode termination (eight consecutive beats outside the detection zones) was fulfilled.

Figure 6-7. Redetection of VT After Therapy

VT and VF Therapy Efficacy

A therapy is considered successful if arrhythmia termination occurs prior to any redetection. The therapy is considered ineffective if redetection occurs before termination.

If all of the programmed therapies are ineffective, the AMD suspends them until either:

- the episode terminates, or
- Detection is manually reset (i.e., you program Detection OFF, and then ON again) during the episode.

In Figure 6-6, the defibrillation therapy was designated as successful because termination precedes redetection.

In Figure 6-7, the arrhythmia episode was redetected before termination. The therapy is therefore designated ineffective, and the next VT therapy will be delivered.

Atrial Therapies

7

Atrial Defibrillation

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Atrial Defibrillation Overview

The AMD provides up to five automatic, biphasic defibrillation shocks to treat a detected episode of AF, and up to three automatic, biphasic defibrillation shocks to treat a detected episode of AT. Each defibrillation shock has a separately programmed energy, pathway, and synchronization.

When an atrial episode meets the requirements for a programmed defibrillation therapy, the AMD charges the high voltage capacitors (page 8-10) to the programmed energy and attempts to synchronize the shock to a sensed event outside the ventricle's vulnerable period.

- If you select "V ONLY" synchronization, the shock is synchronized to a non-refractory ventricular event if possible, or aborts if it cannot be synchronized (see page 7-15).
- If you select "A+V" synchronization, the pulse is synchronized to an atrial or ventricular event outside the ventricular vulnerable period if possible, or aborts if it cannot be synchronized (see page 7-18).

The AMD automatically regulates the pulse width to obtain the programmed tilt. Waveform is not programmable in the AMD; all high voltage therapies use the biphasic waveform. See page 8-4 for a description of Energy, Pathway, and Tilt parameters.

Patient-Activated Defibrillation

The patient can request a defibrillation shock using the hand-held Model 9464 Activator. A patient-activated defibrillation shock is delivered only if the AMD confirms that either AF or AT is present, and only if it can synchronize to a ventricular event.

Atrial Therapy Sequencing

Depending on the programmed atrial therapy sequencing values, atrial therapies may not be delivered in the order they are listed on the programmer screen. Atrial therapies are delivered according to the length of the episode and the rhythm classification during the episode.

◆ **How Atrial Therapy Sequencing Works**

During an AF/AT episode, the AMD updates the atrial rhythm classification on each ventricular event, based on the median atrial cycle length and the AF/AT Evidence counter.

When the AF/AT episode reaches the first programmed Sustained Duration value, the therapies in that tier (e.g., pacing therapies) for both AF and AT become available for delivery (see page 7-7). The AMD can then initiate the first available AF or AT therapy, according to the current atrial rhythm classification.

Upon redetection, the next available AF or AT therapy can be initiated, according to the current atrial rhythm classification at the time of redetection.

If the AF/AT episode duration reaches the second Sustained Duration value, the second tier of AF and AT therapies (e.g., defibrillation) becomes available for delivery (see page 7-8), taking priority over the first tier (the shorter value; e.g., pacing). After a therapy with a longer Sustained Duration value has been initiated, any remaining sequences of first-tier therapies are suspended for that rhythm classification (AF or AT) for the remainder of the episode.

For example, when an AF atrial defibrillation therapy is initiated, any remaining sequences of first tier AF pacing therapies are suspended for an AF rhythm classification until atrial episode termination is detected. However, initiation of an AF therapy does not prevent the delivery of AT therapies with shorter Sustained Duration values, and *vice versa*.

Atrial Therapy Sequencing Parameters

AF/AT Sustained Duration Criterion

If the AF/AT episode fails to terminate spontaneously within the programmed Duration of Sustained AF/AT Required to Initiate Therapy, the AMD can initiate the first programmed atrial pacing or defibrillation therapy, as appropriate. The Duration of Sustained AF/AT values are programmed separately for pacing therapies and defibrillation therapies. However, the programmed values apply to both AF and AT therapies.

◆ **Programmable Parameters**

DURATION OF SUSTAINED AF/AT REQUIRED TO INITIATE THERAPY	AF/AT pacing and defibrillation therapies cannot be delivered until the episode duration exceeds the Pacing Therapies or A-Defib Therapies value, respectively.
---	---

◆ **How the Sustained Duration Timer Works**

At preliminary AF/AT detection, the AMD starts a sustained duration timer. If AF/AT episode duration exceeds the programmed duration required to initiate therapy, the AMD can initiate the first programmed atrial pacing or defibrillation therapy, as appropriate (see page 7-7 and page 7-8).

Note: The sustained duration timer continues throughout AT/AF therapy delivery and redetection. It resets to zero upon AT/AF episode termination.

Daily Availability Window

To minimize discomfort to the patient, you can program the AMD to deliver automatic atrial defibrillation therapies only during selected hours of the day or night. You can also limit the number of shocks the AMD can deliver during a single 24-hour cycle.

◆ **Programmable Parameters**

Maximum A-Defibs (per window)	Number of automatic shocks allowed during the availability window each day.
A-Defib Window Start	24-hour clock time to begin the availability window.
A-Defib Window Length	Duration of the daily availability window.

◆ **How the Daily Availability Window Works**

Maximum A-Defibs per window – When the number of delivered atrial defibrillation therapies (automatic or patient-activated) reaches the programmed Maximum A-Defibs value, further automatic atrial defibrillation attempts are suspended until the next availability window starts.

Window Start and Window Length – If you program the Window Length to 24:00, automatic shocks can be delivered at any time of day.

Patient-activated and EP Study therapies remain available regardless of the Daily Availability Window programming.

Time to Stop Therapy

To limit therapy delivery for a prolonged AF or AT episode, you can program the Time to Stop Therapy. If an AT/AF episode exceeds the programmed value, this feature suspends all AF and AT therapies, including Patient-Activated Defibrillation, for the duration of the AF/AT episode. AF and AT therapies are re-enabled upon AF/AT episode termination.

◆ Programmable Parameters

Time to Stop Therapy	Suspends all AF and AT therapies for the duration of an episode (including patient-activated defibrillation) if the sustained duration of an AT/AF episode is longer than the programmed value.
-----------------------------	---

Requirements for Initiation of Automatic Atrial Pacing Therapy

Once AF/AT episode duration has reached the programmed Duration of Sustained AF/AT Required to Initiate Pacing Therapies, and the rhythm classification is AF or AT, all of the following conditions must **also** be met in order for the AMD to initiate an automatic atrial pacing therapy:

- A:V conduction is at least 2:1, and the last two atrial events are less than the ATDI,¹
- AF/AT episode duration has not exceeded the programmable Time to Stop Therapy (page 7-6), if enabled, and
- For an AF pacing therapy, at least 4 minutes have elapsed since an A-Burst+ or A-Ramp therapy was delivered (to allow post-ATP atrial fibrillation to terminate spontaneously).

1. AFDI, if AT Detection is OFF.

Requirements for Initiation of Automatic Atrial Defibrillation Therapy

Once AT/AF episode duration has exceeded the programmed Duration of Sustained AF/AT Required to Initiate A-Defib Therapies, and the rhythm classification is AF or AT, all of the following conditions must **also** be met in order for the AMD to initiate an automatic atrial defibrillation therapy:

- A:V conduction is at least 2:1, and the last two atrial events are less than the ATDI,¹
- At least two of the most recent twelve ventricular intervals are greater than or equal to the programmed A-Defib Ventricular Refractory Period (page 7-14, page 7-16),
- The A-Defib Daily Availability criteria must be satisfied (page 7-5),
- AT/AF episode duration has not exceeded the programmable Time to Stop Therapy, if enabled (page 7-6), and
- For an AF defibrillation therapy, at least 4 minutes have elapsed since an A-Burst+ or A-Ramp therapy was delivered (to allow post-ATP atrial fibrillation to terminate spontaneously).

Atrial High Voltage Abort – If the episode has already included 15 aborted atrial shocks, the atrial defibrillation therapy aborts. This requirement protects the device's longevity by limiting ineffective high voltage charges.

Note: For Submodel 0 devices and devices without a submodel,² if the first automatic atrial defibrillation therapy is aborted, it will not be re-initiated if redetection occurs. It is also possible that no other atrial defibrillation therapies for the particular rhythm classification (i.e., AF or AT) will be initiated during the episode.

1. AFDI, if AT Detection is OFF.
2. If applicable, the device submodel is displayed on the Serial Number screen (**PARAMETERS** menu) and the Circuit Status screen (**DATA** menu).

Programming Automatic Atrial Defibrillation

Atrial defibrillation can be programmed as AF Therapies 2 - 6, and for AT Therapies 4 - 6.

◆ **Programmable Parameters**

Energy (J)	Energy level for the defibrillation therapy (see page 8-4).
Pathway	Designates which electrodes are to be anode(s) and cathode(s) (see page 8-4).
Synchronization	Delivers the shock on an atrial event or on a ventricular event.
Tilt (%)	Voltage decay during each phase of the shock* (see page 8-5).
A-Defib V. Refract	Ventricular refractory period (VRP) used to prevent delivery during the ventricle's vulnerable period.*
DURATION OF SUSTAINED AF/AT REQUIRED TO INITIATE THERAPY	AT/AF therapy is withheld until the episode duration exceeds the programmed duration required for atrial defibrillation therapies (see page 7-4).
Maximum A-Defibs (per window)	Number of shocks allowed during the availability window each day (see page 7-5).
A-Defib Window Start	24-hour clock time to start the availability window.
A-Defib Window Length	Duration of the daily availability window.
Time to Stop Therapy	Suspends all AF and AT therapies for the duration of an episode (including patient-activated defibrillation) if the AT/AF episode persists for longer than the programmed value (see page 7-6).

* Programmed in common for all automatic and patient-activated atrial defibrillation.

Atrial Therapies

Programming Automatic Atrial Defibrillation

◆ How to Program Automatic Atrial Defibrillation

1. From the **PARAMETERS** menu, select the **THERAPIES** menu option and then the **AF/AT** button.
 - a. To program the defibrillation parameters, select next to the appropriate therapy number; for example, next to (2.) in the "AF Therapies" column for AF Therapy 2.
 - b. To program the **DURATION OF SUSTAINED AF/AT REQUIRED TO INITIATE THERAPY**, **A-DEFIB DAILY AVAILABILITY WINDOW**, and **Time to Stop Therapy** features, select next to the appropriate parameter.
2. To program defibrillation **Tilt (%)** and the **ADefib. V. Refract**, select the **SHARED** button.

Automatic Atrial
Defibrillation Parameters
(circled)

DATA	TESTS	PARAMETERS	END SESSION	SPECIAL	PRINT
Programming confirmed.					
VF	VT	AF/AT	PATIENT	SHARED	
DURATION OF SUSTAINED AF/AT REQUIRED TO INITIATE THERAPY Pacing Therapies: 5 min A-Defib Therapies: 1 hr			A-DEFIB DAILY AVAILABILITY WINDOW Maximum A-Defibs (per window): 1 A-Defib Window Start: 03:00 A-Defib Window Length: 24 hrs Current System Time = 12:14		
Time To Stop Therapy: 48 hrs					
AF THERAPIES 1. PACING (HIGH-FREQ) 20 2. A-DEFIB 1.0 CAN+S1>BV 3. A-DEFIB 2.0 CAN+S1>BV 4. Skip 5. Skip 6. Skip			AT THERAPIES 1. PACING (ARMP) 6 2. PACING (ARMPST+) 6 3. PACING (HIGH-FREQ) 5 4. A-DEFIB 1.0 CAN+S1>BV 5. A-DEFIB 2.0 CAN+S1>BV 6. Skip		

DATA	TESTS	PARAMETERS	END SESSION	SPECIAL	PRINT
SHARED THERAPY PARAMETERS: Select parameters and then select PROGRAM.					
VF	VT	AF/AT	PATIENT	SHARED	
SHARED ATRIAL THERAPY PARAMETERS: Pulse Width(ms): 1.5 Tilt(CZ): 50 Amplitude(V): 8 ADefib V. Refract: 400 Pace Blank(ms): 250 Min. A-A Interval (ms): 150					

Figure 7-1. AF/AT and Shared Therapy Screens (partial)

Programming Patient-Activated Atrial Defibrillation

To allow the patient and physician greater control over atrial defibrillation therapy delivery, the patient can use the Model 9464 Activator to instruct the AMD to deliver atrial defibrillation therapy.

◆ **Programmable Parameters**

Therapy Status	ON or OFF
Energy (J)	Stored energy level for the defibrillation therapy (see page 8-4).
Pathway	Designates which electrodes are to be anode(s) and cathode(s) (see page 8-4).
Synchronization	Delivers the shock on an atrial event or on a ventricular event.
Tilt (%)	Voltage decay during each phase of the shock* (see page 8-5).
A-Defib V. Refract	Ventricular refractory period (VRP) used to prevent delivery during the ventricle's vulnerable period.*

* Programmed in common for all automatic and patient-activated atrial defibrillation.

Atrial Therapies

Programming Patient-Activated Atrial Defibrillation

◆ How to Program Patient-Activated Defibrillation

1. From the **PARAMETERS** menu, select the **THERAPIES** menu option.
2. To program the defibrillation parameters, select the **PATIENT** button.
3. To program defibrillation tilt and refractory period, select the **SHARED** button.

DATA	TESTS	PARAMETERS	END SESSION	SPECIAL	PRINT
------	-------	------------	-------------	---------	-------

PATIENT ACTIVATED THERAPY: Select parameters and then select PROGRAM.

VF	VT	AF/AT	PATIENT	SHARED
----	----	-------	---------	--------

PATIENT ACTIVATED A-DEFIB THERAPY

Therapy Status: ON
Energy(J): 2.0
Pathway: CAN+S1>BV
Synchronization: U ONLY

Patient-Activated Atrial
Defibrillation Parameters
(circled)

DATA	TESTS	PARAMETERS	END SESSION	SPECIAL	PRINT
------	-------	------------	-------------	---------	-------

SHARED THERAPY PARAMETERS: Select parameters and then select PROGRAM.

VF	VT	AF/AT	PATIENT	SHARED
----	----	-------	---------	--------

SHARED ATRIAL THERAPY PARAMETERS:

Pulse Width(ms):	1.5	Tilt(CZ):	50
Amplitude(V):	8	ADefib U. Refract:	400
Pace Blank(ms):	250		
Min. A-A Interval (ms):	150		

Figure 7-2. Patient and Shared Therapy Screens (partial)

◆ **How Patient-Activated Defibrillation Works**

At least one VF therapy must be enabled if patient-activated atrial defibrillation is enabled.

A patient-activated atrial defibrillation is delivered only if the AMD verifies that AF or AT is present at the time of the telemetry command, and if it is able to synchronize to a ventricular event. A pending patient-activated defibrillation takes priority over automatic AF and AT therapy.

A patient-activated atrial defibrillation is not delivered if any of the following occur:

- the AF or AT episode has terminated, including detection of VF or VT (see page 5-13).
- the Time to Stop Therapy timer has elapsed (see page 7-6).
- the AMD is unable to synchronize the patient-activated shock.
- more than 60 seconds have elapsed since triggering by the patient activator.

Atrial Defibrillation Synchronization

Note: Since the AMD's high voltage pulses are synchronized to events sensed on the implanted electrodes, monitoring by the surface ECGs will exhibit morphologies and timing that do not necessarily coincide exactly with those taking place at the electrode sites.

Ventricular-Only Synchronization

In V-ONLY synchronization, atrial defibrillation is synchronized to a non-refractory ventricular event, if possible. If the Lower Rate V-V interval expires, the shock is delivered then. The shock aborts in the presence of a high ventricular rate to prevent delivery during the vulnerable period preceding ventricular depolarization.

◆ Programmable Parameters

Synchronization	V-ONLY.
A-Defib V. Refract	Ventricular refractory period (VRP) used to prevent delivery during the ventricle's vulnerable period.

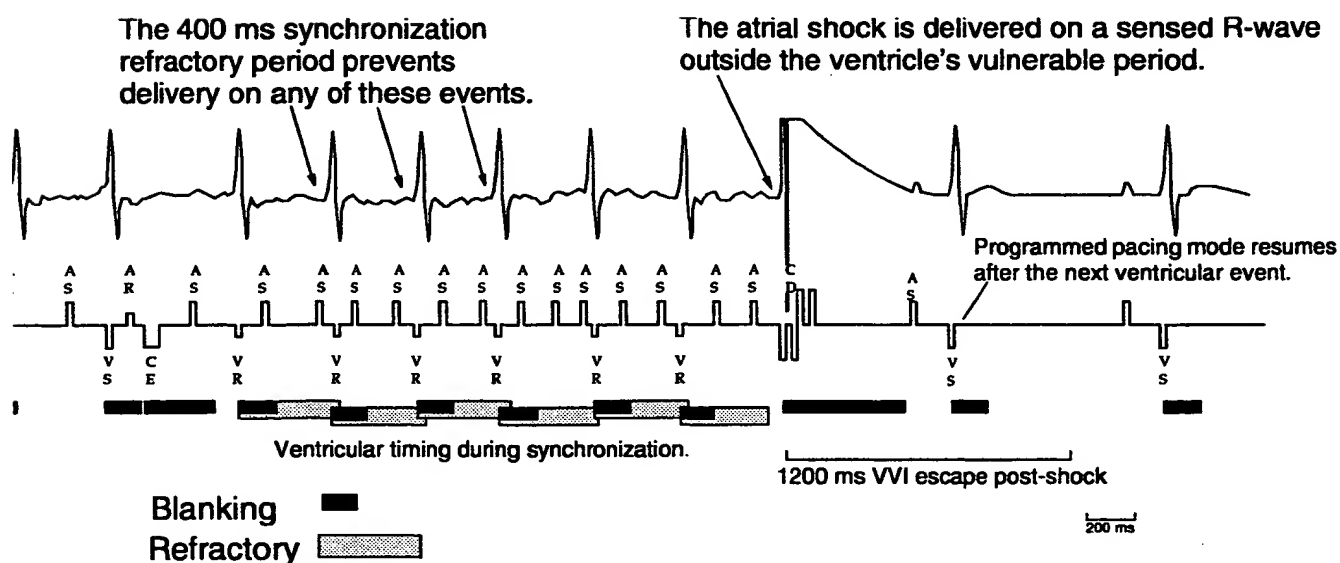


Figure 7-3. V-ONLY Atrial Synchronization

◆ **How V-Only Atrial Defibrillation Synchronization Works**

During V-ONLY synchronization, the AMD operates in VVI pacing mode at the programmed lower rate: all synchronization timing occurs in the ventricle only.

V-ONLY defibrillation does not require an R-wave: the atrial shock is delivered asynchronously in the absence of ventricular activity (unless pacing is programmed OFF).

The AMD uses a synchronization interval, equal to the Lower Rate pacing interval,¹ to identify the R-wave for delivering the shock. Each synchronization interval begins with a post-sense or post-pace ventricular blanking period (see “Blanking Periods” on page 4-6), and the A-Defib ventricular refractory period as programmed.

After the post-charge blanking period (page 8-10), the first synchronization interval begins at the next sensed or paced ventricular event. A refractory ventricular event during synchronization restarts the synchronization interval.

- At the first non-refractory ventricular event during synchronization (i.e., not the event immediately after charging), the atrial defibrillation therapy is delivered. (Figure 7-3). If the synchronization interval (Lower Rate escape interval) **times out**, the therapy is delivered then.
- If **twelve refractory sensed ventricular events** occur before the therapy is delivered, the shock aborts. These 12 events could include the event immediately after charging ends.

1. 1760 ms if bradycardia pacing is programmed OFF. When pacing is OFF, the shock aborts if any 1760 ms escape interval expires.

“A+V” Synchronization

In A+V synchronization, the AMD synchronizes to a non-refractory (i.e., outside the ventricular vulnerable period) P-wave or R-wave. The shock aborts in the presence of a high ventricular rate to prevent its being delivered during the vulnerable period preceding ventricular depolarization.

◆ **Programmable Parameters**

Synchronization	A + V.
A-Defib V. Refract	Ventricular refractory period (VRP) used to prevent delivery during the ventricle’s vulnerable period.

◆ **Programming Considerations**

The post-ventricular atrial refractory period during synchronization (A-Defib ARP) is established as the programmed A-Defib VRP plus 50 ms.

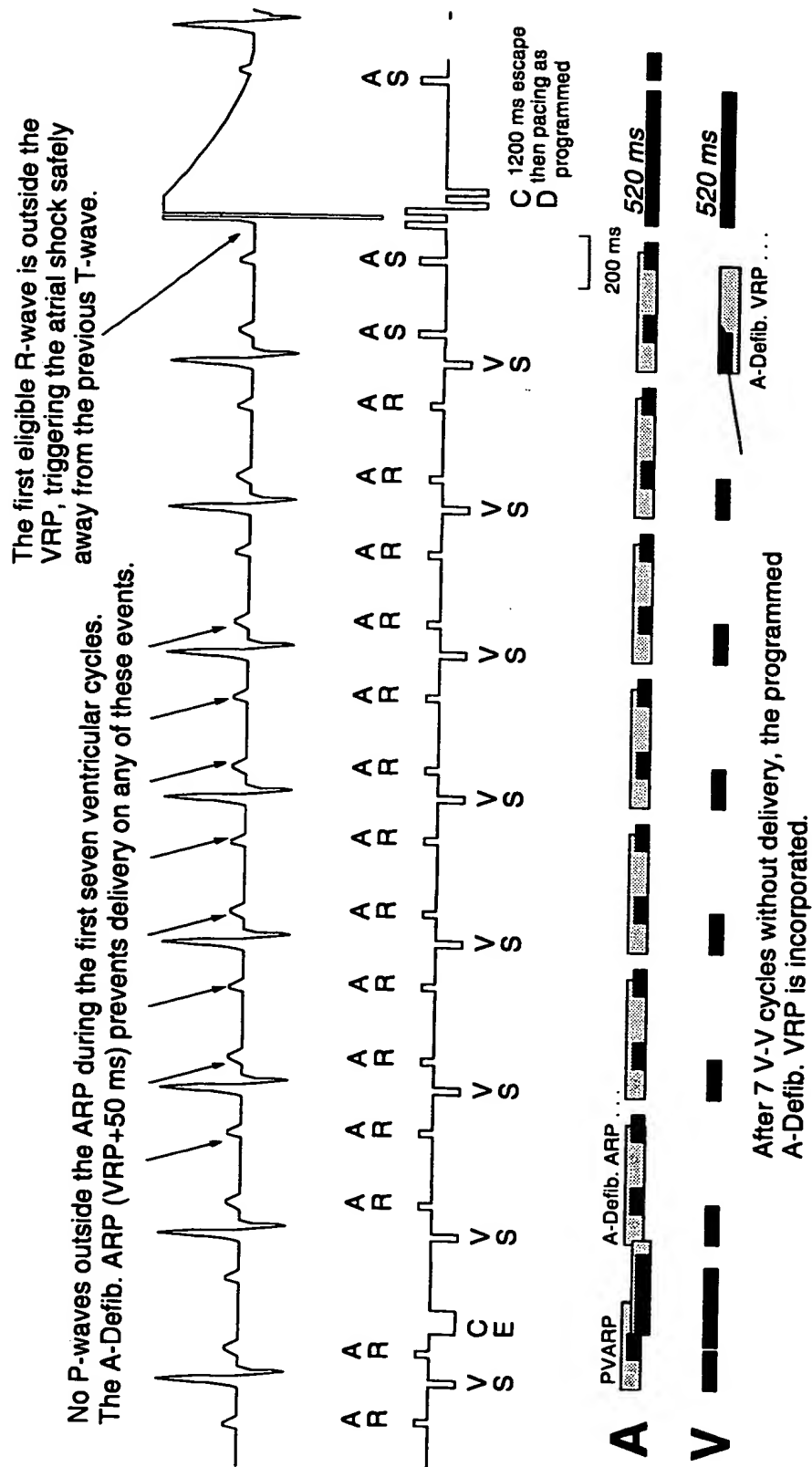


Figure 7-4. A+V Atrial Synchronization

◆ **How “A+V” Atrial Defibrillation Synchronization Works**

The AMD uses programmable post-ventricular refractory periods to protect against delivery of atrial shocks during the ventricle’s vulnerable period. The atrial shock is delivered asynchronously in the absence of ventricular activity.¹

- After the post-charge blanking period, synchronization begins at the next ventricular event. At the first **non-refractory atrial event** (i.e., outside the A-Defib ARP), the AMD synchronizes and delivers the therapy. Atrial events sensed during the A-Defib ARP are disregarded.
- Each subsequent ventricular event restarts a new synchronization window. If the Lower Rate interval times out without a ventricular event, the AMD paces the ventricle and attempts to synchronize to a non-refractory atrial event.

If the shock is not delivered within six ventricular cycles, the search is broadened to include non-refractory ventricular events.

- At the next **non-refractory event in either chamber**, the atrial defibrillation therapy is delivered (Figure 7-4). If the **Lower Rate interval times out**, the shock is delivered then.
- If **six refractory sensed ventricular events** occur before the therapy is delivered, the shock aborts. (Note that there is no A-Defib VRP during the first six synchronization cycles.)

1. When pacing is OFF, the shock aborts if any 1760 ms escape interval expires.

Events Following an Atrial Shock

Following a delivered atrial defibrillation therapy, the following begin immediately:

- a post-shock blanking period of 520 ms in each chamber.
- one VVI pacing cycle at 50 ppm (escape interval of 1200 ms).¹

After the first ventricular event, the programmed bradycardia pacing mode resumes, using the post-shock output settings (1.5 ms, 6 V—see page 4-9).

The AMD monitors for an outcome to the delivered therapy, either episode termination or redetection. If VT or VF is redetected following an atrial therapy delivery, all AF and AT therapies (automatic and patient-activated) are disabled until you reinstate them with the programmer.

The AMD records in the Episode Data Report whether or not the defibrillation therapy was successful. It also increments one of the Therapy Counters in the Counter Data Report. The AMD maintains separate counters of successful, ineffective, and aborted attempts for each programmed therapy.

After an Aborted Atrial Shock

Following an aborted atrial defibrillation therapy or charging period, the AMD reverts to its programmed prevention, detection, and pacing settings. If the AMD redetects the same atrial arrhythmia after an aborted therapy, it tries to synchronize and deliver the same therapy, up to a limit of 15 aborted shocks for a single episode.

If an atrial defibrillation therapy aborts, leaving the energy stored on the capacitors, the delivered energy of a subsequent high voltage therapy could be higher than the programmed value.

1. If Bradycardia Pacing is programmed OFF, there is no pacing.

Atrial Pacing Therapies

All atrial pacing therapies share the following characteristics:

- The pulse width, amplitude, and pace blanking period are the same for all atrial antitachycardia (ATP) therapies, but are programmed separately from the ventricular ATP and the bradycardia pacing values. These values are programmed from the **SHARED** therapy parameters screen.
- After each atrial pacing sequence, the AMD must redetect the original atrial arrhythmia before it will deliver the next sequence. If a different arrhythmia is redetected, the AMD delivers the next programmed therapy for the current arrhythmia.
- Atrial pacing therapies are synchronized to the first atrial event after the ventricular event upon which the atrial arrhythmia is detected (or redetected).
- The nominal settings for ATP therapies are based on clinical experience and previous research in antitachycardia pacing. When an ATP therapy is enabled, decide whether to use nominal values or to program new values. Verify the effectiveness of any ATP therapy at the time it is enabled.
- Backup ventricular pacing is not available during atrial pacing therapy delivery.

Atrial Burst+ and Atrial Ramp therapies also share the following characteristics, which are not shared by 50 Hz Burst pacing:

- The A-Burst+ and A-Ramp pacing intervals are rate adaptive to the average of the last four P-P intervals prior to detection or redetection.
- A-Burst+ and A-Ramp pulses are never delivered at less than the programmed atrial ATP minimum interval. This minimum pacing interval is the same for all A-Burst+ and A-Ramp therapies. If the calculated interval is shorter than the programmed minimum, the pulses are delivered at the programmed minimum interval.
- A-Burst+ and A-Ramp therapies cannot be delivered as programmed if the tachycardia cycle length is too short. See "Rate Limited Atrial ATP Therapies" on page 7-30.

A-Burst+ Pacing

A-Burst+ therapy consists of a programmable number of sequences of AOO bursts, followed by two premature extrastimuli delivered at programmable intervals..

See page 7-28 for programming instructions.

◆ **Programmable Parameters**

INITIAL # PULSES	Number of S1 pulses in each burst sequence.
A-S1 INTERVAL S1-S2 INTERVAL S2-S3 INTERVAL }	Pacing intervals of the S1 burst sequence, and the S2 and S3 extrastimuli following the burst, as a percentage of the pre-therapy atrial interval average.
INTERVAL DEC	Pacing interval decrement per sequence.
# SEQUENCES	Number of sequences in the therapy.
MINIMUM A-A INTERVAL	Minimum interval for all atrial ATP therapies.

◆ **How A-Burst+ Pacing Works**

The Burst+ sequence is delivered at the programmed S1 Interval, timed from the sensed event that fulfills detection; the first extrastimulus is delivered at the S1-S2 percentage; the second extrastimulus is delivered at the S2-S3 percentage. Each time the tachycardia is redetected after an ineffective sequence, the AMD applies the programmed Burst+ percentages to the new cycle length, and then subtracts the programmed interval decrement (once per sequence) to calculate the pacing intervals for the next Burst+ sequence (see Figure 7-5).

Note: Ventricular back-up pacing is not available during A-Burst+ pacing.

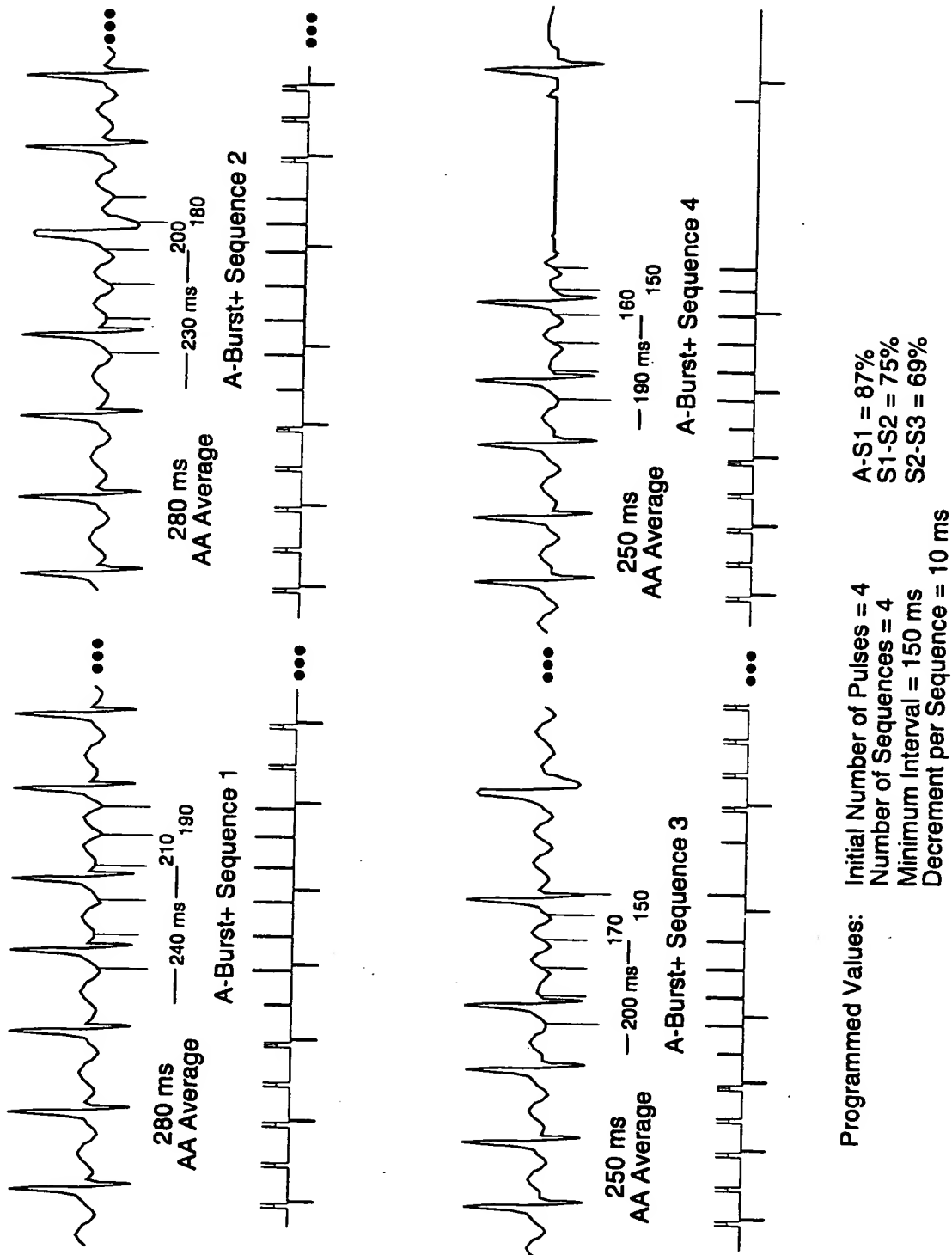


Figure 7-5. A-Burst+ Pacing Operation

A-Ramp Pacing

A-Ramp therapy consists of a programmable number of sequences of AOO pulses delivered at decreasing intervals.

See page 7-28 for programming instructions.

◆ **Programmable Parameters**

INITIAL # PULSES	Number of pulses in the first A-Ramp sequence.
A-S1 INTERVAL	Pacing interval of the first A-Ramp pulse, as a percentage of the pre-therapy atrial cycle length.
INTERVAL DEC	Pacing interval decrement per pulse for the remaining A-Ramp pulses in each sequence.
# SEQUENCES	Number of sequences in the A-Ramp therapy.
MINIMUM A-A INTERVAL	Minimum pacing interval for all atrial ATP therapies.

◆ **How A-Ramp Pacing Works**

The first pulse of each A-Ramp sequence is delivered at a programmable percentage of the current AT cycle length. The rest of each sequence is delivered at progressively shorter intervals, based on the programmed interval decrement. Each time the tachycardia is redetected after an ineffective sequence, the AMD applies the programmed Ramp percentage to the new cycle length, and adds one additional pacing pulse per sequence (see Figure 7-6).

Note: Ventricular back-up pacing is not available during A-Ramp pacing.

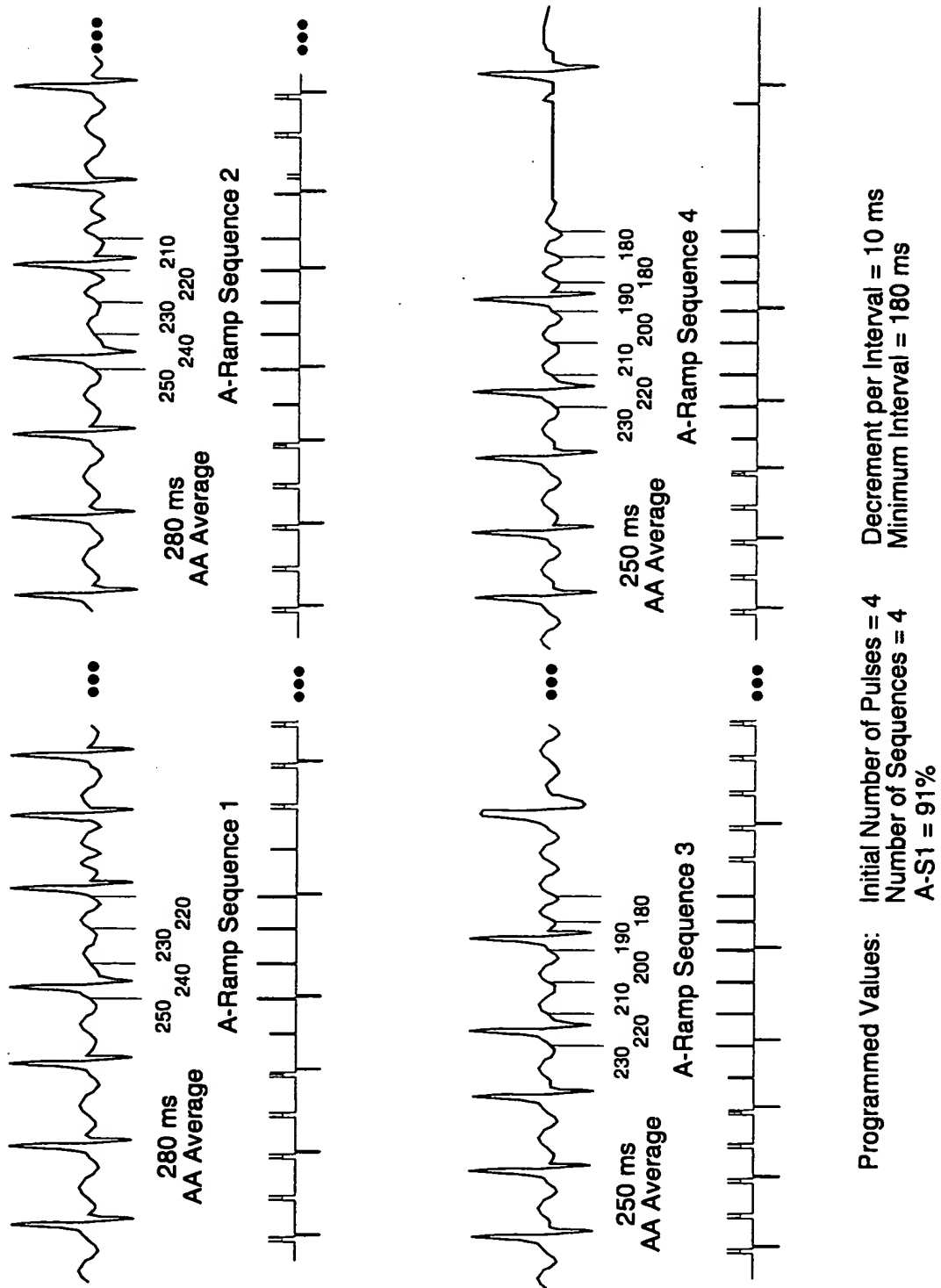


Figure 7-6. A-Ramp Pacing Operation

A-50 Hz Burst Pacing

A-50 Hz Burst (high frequency) sequence delivers a burst of AOO pulses at 20 ms intervals for a programmable duration. A-50 Hz Burst therapy consists of a programmable number of burst sequences.

See page 7-28 for programming instructions.

◆ **Programmable Parameters**

# SEQUENCES	Number of sequences in the therapy.
BURST DURATION	Duration of each 50 Hz burst pacing sequence.

◆ **How A-50 Hz Burst Pacing Works**

Each sequence delivers AOO pulses at 20 ms intervals for the programmed number of seconds. Each time the AF or AT is redetected, the AMD delivers another identical Burst sequence, up to the programmed number of sequences (see Figure 7-7).

AF Detection and AT Detection are suspended for 16 ventricular events after each sequence of an A-50 Hz Burst therapy.

Note: Ventricular back-up pacing is not available during A-50 Hz Burst pacing.

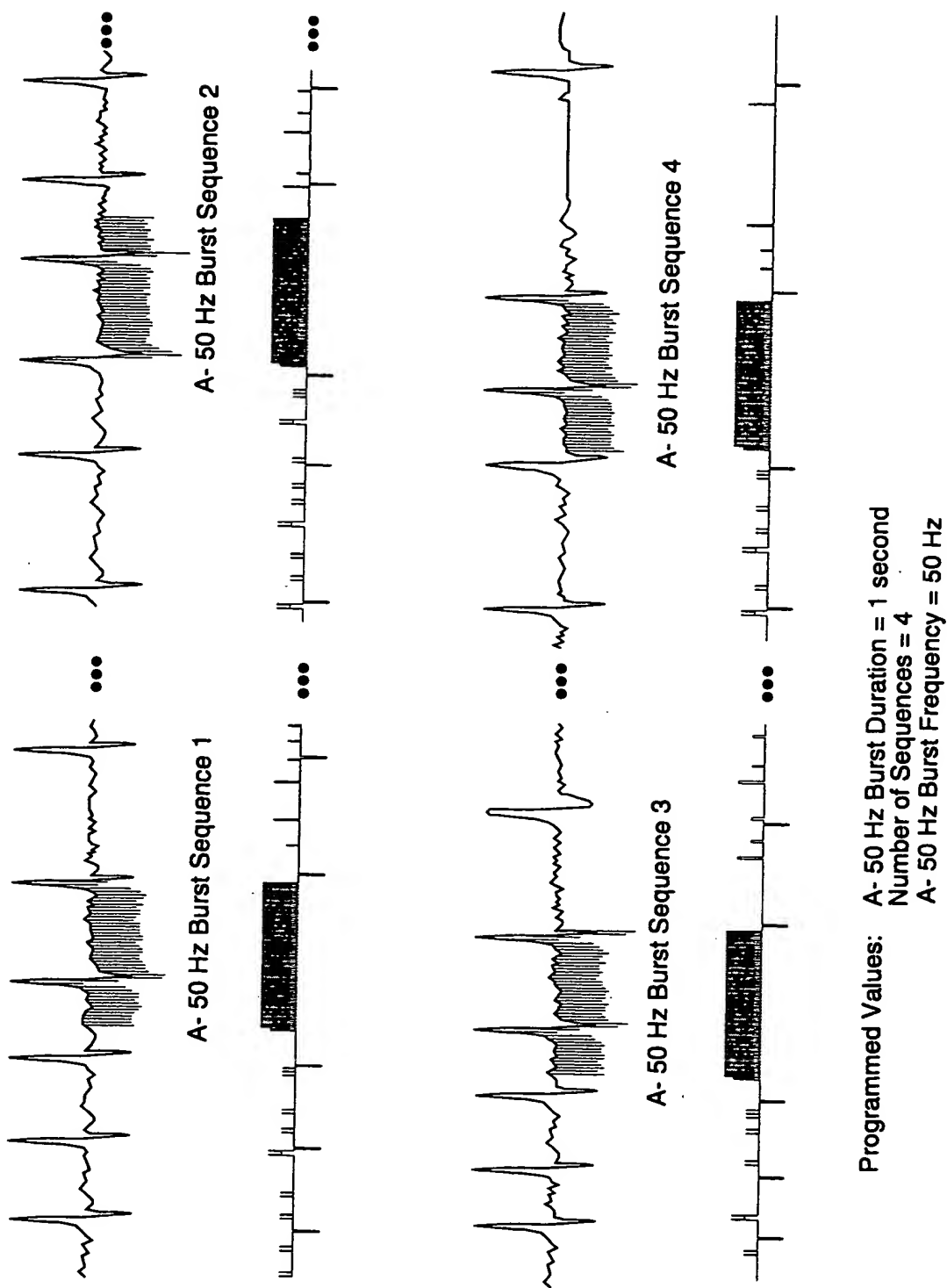


Figure 7-7. A-50 Hz Burst Pacing Operation

Programming Atrial Pacing Therapies

◆ **Atrial Pacing Therapy Availability**

	Available for therapies:
A-Burst+	AT Therapies 1 and 2
A-Ramp	AT Therapies 1 and 2
A-50 Hz Burst (High Freq)	AF Therapy 1, AT Therapy 3

◆ **How to Program Atrial Pacing Therapies**

1. From the **PARAMETERS** menu, select the **THERAPIES** menu option and then the **AF / AT** button.
 - a. To program **AF** pacing therapy, select next to (1.) in the "AF Therapies" column for AF Therapy 1, and set parameters.
 - b. To program an **AT** pacing therapy, select next to (1.), (2.), or (3.) in the "AT Therapies" column, and set parameters.
 - c. To program the **DURATION OF SUSTAINED AF/AT REQUIRED TO INITIATE THERAPY** and **Time to Stop Therapy** features, select next to the appropriate parameter.
2. To program pulse output parameters for all atrial pacing therapies, select the **SHARED** button.

See Figure 7-8 for AF/AT and Shared programming screens.

Atrial Therapies

Atrial Pacing Therapies

Automatic
Atrial Pacing Parameters
(circled)

DATA	TESTS	PARAMETERS	END SESSION	SPECIAL	PRINT
Programming confirmed.					
UF	UT	AF/AT	PATIENT	SHARED	
DURATION OF SUSTAINED AF/AT REQUIRED TO INITIATE THERAPY			A-DEFIB DAILY AVAILABILITY WINDOW		
Pacing Therapies: 5 min			Maximum A-Defibs (per window): 1		
A-Defib Therapies: 1 hr			A-Defib Window Start: 03:00		
			A-Defib Window Length: 24 hrs		
			Current System Time = 12:14		
Time To Stop Therapy: 48 hrs					
AF THERAPIES			AT THERAPIES		
1.	PACING (HIGH-FREQ) 20		1.	PACING (ABAMP) 6	
2.	A-DEFIB 1.0 CAN+S1>MU		2.	PACING (ABURST+) 6	
3.	A-DEFIB 2.0 CAN+S1>MU		3.	PACING (HIGH-FREQ) 5	
4.	Skip		4.	A-DEFIB 1.0 CAN+S1>MU	
5.	Skip		5.	A-DEFIB 2.0 CAN+S1>MU	
6.	Skip		6.	Skip	

DATA	TESTS	PARAMETERS	END SESSION	SPECIAL	PRINT
SHARED THERAPY PARAMETERS: Select parameters and then select PROGRAM.					
UF	UT	AF/AT	PATIENT	SHARED	
SHARED ATRIAL THERAPY PARAMETERS:					
Pulse Width(ms):		1.5	Tilt(CX):		50
Amplitude(V):		8	ADefib U. Refract:		400
Pace Blank(ms):		250			
Min. A-A Interval (ms):		150			

Figure 7-8. AF/AT and Shared Therapy Screens (partial)

Cancelled Atrial Pacing Therapies

Rate Limited Atrial ATP Therapies

A-Ramp and A-Burst+ pacing pulses are never delivered at less than the programmed minimum pacing interval. If the detected AT cycle length is less than or equal to the programmed minimum pacing interval, the AMD cannot deliver any pacing therapy that will overdrive the intrinsic rate. The AMD skips to the next available AT therapy (A-50 Hz or A-Defibrillation¹). If neither therapy is enabled for AT, the AMD does not deliver any AT therapy.

VF or VT Detected During an Atrial Pacing Therapy

If a ventricular tachyarrhythmia is detected after delivery of an atrial therapy (i.e., before either AF/AT redetection or AF/AT episode termination), the remaining sequences of the atrial therapy are not delivered. Instead, the AMD disables all atrial therapies and delivers the first programmed therapy for the ventricular arrhythmia.

1. A-Defib therapy can only be initiated if the programmed Duration of Sustained AF/AT Required to Initiate A-Defib Therapies is met.

Ventricular Therapies

8

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Cardioversion Overview 8-2***

***Defibrillation and Cardioversion
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Ventricular Defibrillation and Cardioversion Overview

Defibrillation and cardioversion are the two high voltage ventricular therapies. The AMD provides up to six defibrillation shocks to treat a detected episode of VF, and up to six cardioversion shocks to treat a detected episode of VT.

When a ventricular arrhythmia is detected and defibrillation or cardioversion is the next programmed therapy, the AMD charges the high voltage capacitors to the programmed energy. When the programmed energy is reached, the AMD attempts to synchronize the pulse to the leading edge of a ventricular sensed event. In general:

- a defibrillation pulse is timed to the first non-refractory sensed event if possible, or delivered asynchronously if it cannot be synchronized.
- a cardioversion pulse is timed to the first non-refractory sensed event (not including the first event after charging ends) if possible, or aborted if it cannot be synchronized.

Programmable Defibrillation Parameters

Each therapy of ventricular defibrillation or cardioversion has separately programmed energy and pathway (see page 8-4). Tilt is selected in common for all ventricular defibrillation and cardioversion therapies.

The AMD automatically regulates the pulse width to obtain the programmed tilt. Waveform is not programmable in the AMD; all high voltage therapies use the biphasic waveform.

Comparison of Defibrillation and Cardioversion

A defibrillation shock is delivered only for VF; a cardioversion shock is delivered only for VT.

In defibrillation, the AMD attempts to synchronize with a sensed R-wave, but does not require such synchronization.

Cardioversion requires synchronization to a sensed R-wave for delivery to occur.

Committed vs. Non-Committed Therapies – The AMD automatically reconfirms VF before delivering the first application of the first programmed defibrillation therapy. Subsequent VF therapies within the same episode are always committed: if the capacitors reach their programmed energy, the shock will be delivered. Cardioversion is a non-committed therapy: If the AMD cannot synchronize to a ventricular sensed event, the therapy aborts.

Table 8-1 summarizes the differences between ventricular defibrillation and cardioversion.

Table 8-1. Comparison of Defibrillation and Cardioversion

Comparison	V-Defibrillation	V-Cardioversion
Episode detected	VF	VT
Charging period	Same	Same
Reconfirm arrhythmia	First available therapy only; subsequent therapies are committed	All therapies non-committed (require synchronization)
R-Wave Synchronization	Not required	Required
Modify timing of synchronization	Not possible	CV Delay parameter allows shift relative to sensed event (manual therapies only)
Synchronization successful	Deliver at first non-refractory sensed event after charging	Deliver at second non-refractory sensed event (if possible)
Synchronization unsuccessful	Deliver asynchronous defibrillation pulse at end of synchronization sequence	Abort CV pulse

Defibrillation and Cardioversion Parameters

Energy

The AMD can be programmed to deliver up to 27 joules.¹ Defibrillation or cardioversion energy level is selected independently for each therapy.

Pathway

Each therapy can be programmed with any configuration of the implanted electrodes as anode(s) and cathode(s), with one restriction: the CAN and RVC electrodes, if used, must be opposed to each other.

The nominal ventricular pathway is CAN > RVC; the nominal atrial pathway is CAN + SV1 > RVC. The RV coil must be connected to the RVC port.

1. Deliverable energy based on a biphasic pulse delivered into a 75 Ω pacing load.

Tilt

The AMD's high voltage pulses are tilt controlled (Figure 8-1): Each phase is truncated when it has decayed by a percentage of its initial value, or "tilt." Tilt is programmed in common for all automatic therapies, and separately for each manual therapy.¹

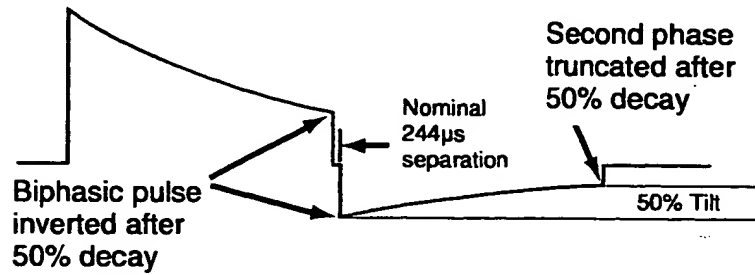


Figure 8-1. Biphasic Defibrillation/Cardioversion Waveform

1. A separate tilt value is programmed in common for all automatic atrial defibrillation therapies.

Programming Ventricular Defibrillation

◆ **Programmable Parameters**

VF THERAPY STATUS	ON or OFF.*
ENERGY (J)	Energy level for the defibrillation therapy.
PATHWAY	Designates which electrodes are to be anode(s) and cathode(s) (see page 8-4).
TILT (%)	Voltage decay during each phase of the shock (see page 8-5).

* Any of the six VF therapies can be programmed OFF. The AMD retains the settings, but skips the "off" therapy and immediately delivers the next available therapy.

◆ **Programming Considerations**

No more than the first of the six VF Therapies should be programmed to less than 27 joules.

◆ **How to Program Ventricular Defibrillation**

1. From the **PARAMETERS** menu, select the **THERAPIES** menu option.
2. To program the defibrillation parameters, select the **VF** button.
3. To program Tilt (%), select the **SHARED** button.

DATA	TESTS	PARAMETERS	END SESSION	SPECIAL	PRINT	
VF THERAPIES: Select parameters and then select PROGRAM.						
VF	VT	AF/AT	PATIENT	SHARED	SHOW PRESENT	
		1	2	3	4	5 6
VF Therapy Status:		ON	ON	ON	ON	ON
Energy(J):		27	27	27	27	27
Pathway:		CAN>BUC	CAN>BUC	CAN>BUC	CAN>BUC	CAN>BUC

Automatic Ventricular
Defibrillation Parameters
(circled)

DATA	TESTS	PARAMETERS	END SESSION	SPECIAL	PRINT	
SHARED THERAPY PARAMETERS: Select parameters and then select PROGRAM.						
VF	VT	AF/AT	PATIENT	SHARED		
SHARED ATRIAL THERAPY PARAMETERS:						
Pulse Width(ms):		1.5	Tilt(%):		50	
Amplitude(V):		8	ADefib V. Refract:		400	
Pace Blank(ms):		250				
Min. A-A Interval (ms):		150				
SHARED VENTRICULAR THERAPY PARAMETERS:						
Pulse Width(ms):		1.5	Tilt(%):		50	
Amplitude(V):		8				
Pace Blank(ms):		250				

Figure 8-2. VF and Shared Therapy Screens (partial)

Programming Ventricular Cardioversion

◆ **Programmable Parameters**

VT THERAPY STATUS	ON or OFF.*
ENERGY (J)	Energy level for the cardioversion therapy.
PATHWAY	Designates which electrodes are to be anode(s) and cathode(s) (see page 8-4).
TILT (%)	Voltage decay during each phase of the shock (see page 8-5).

* Any of the six VT therapies can be programmed OFF. The AMD retains the settings, but skips the "off" therapy and immediately delivers the next available therapy.

◆ **Programming Considerations**

If VT Therapy is ON, VF Therapy must also be ON.

At least one therapy for VT should be programmed to 27 joule cardioversion.

◆ **How to Program Ventricular Cardioversion**

1. From the **PARAMETERS** menu, select the **THERAPIES** menu option.
2. To program the cardioversion parameters, select the **VT** button and select **CV** for Therapy Type.
3. To program Tilt (%), select the **SHARED** button.

Automatic Ventricular
 Cardioversion Parameters
 (circled)

DATA		TESTS		PARAMETERS		END SESSION		SPECIAL		PRINT	
UT THERAPIES: Select parameters and then select PROGRAM.											
VF		UT		AF/AT		PATIENT		SHARED		SHOW PRESENT	
		1		2		3		4		5	
UT Therapy Status:		ON		ON		ON		ON		ON	
Therapy Type:		BURST		BMP		BMP+		CV		CV	
Initial # Pulses:		6		8		3					
S1 Interval-(%RR):		84		91		75					
S1S2(RAMP+)=(%RR):						69					
S2SN(RAMP+)=(%RR):						66					
Interval Dec (ms):		10		10							
# Sequences:		5		5		5					
Energy(J):								27		27	
Pathway:								CAB-BUC		CAB-BUC	

DATA		TESTS		PARAMETERS		END SESSION		SPECIAL		PRINT	
SHARED THERAPY PARAMETERS: Select parameters and then select PROGRAM.											
VF		UT		AF/AT		PATIENT		SHARED			
SHARED ATRIAL THERAPY PARAMETERS:											
Pulse Width(ms):		1.5		Tilt(%):		50					
Amplitude(V):		8		ADefib V. Refract:		400					
Pace Blank(ms):		250									
Min. A-A Interval (ms):		150									
SHARED VENTRICULAR THERAPY PARAMETERS:											
Pulse Width(ms):		1.5		Tilt(%):		50					
Amplitude(V):		8									
Pace Blank(ms):		250									

Figure 8-3. VT and Shared Therapy Screens (partial)

Charging Period



Warning: If the charging time exceeds 30 seconds, replace the AMD to protect against potential loss of AMD function (see “End of Life (EOL) Indicators” on page 13-4).

The capacitor charging time usually varies at implant from less than one second to ten seconds, depending on the programmed stored energy. The charge time lengthens as the battery voltage depletes during the life of the AMD. Furthermore, the high voltage capacitors require a longer charging time as time increases from the last charging period.

A 300 ms blanking period starts at the completion of a charging period.

The telemetry link to the Programmer may be lost during charging.

Charge Circuit Timeout

If a single charging period reaches 30 seconds, the AMD terminates charging, aborts the therapy attempt (but retains the charge on the capacitors), and resumes detection using the programmed detection criteria. The charge circuit is still active. The AMD sends the **CHARGE CIRCUIT TIMEOUT** message via telemetry.

Charge Circuit Inactive

If three consecutive charging periods have each reached 30 seconds, the AMD terminates charging, aborts the therapy attempt, and disables the automatic tachyarrhythmia therapies and manual operations except for Emergency VVI pacing. The charge circuit is inactive. The AMD sends the **CHARGE CIRCUIT INACTIVE** message via telemetry.

Ventricular Synchronization

Note: Since the AMD's high voltage pulses are synchronized to events sensed on the implanted electrodes, monitoring by the surface ECGs will exhibit morphologies and timing that do not necessarily coincide exactly with those taking place at the electrode sites.

Ventricular Defibrillation Synchronization

Defibrillation is synchronized to a sensed R-wave if possible. On the first automatic VF therapy, the shock is not committed. (See "Reconfirm VF" on page 8-13.)

◆ **Programmable Parameters**

Defibrillation synchronization is fully automatic and does not require any programming.

◆ **How Committed Defibrillation Synchronization Works**

Committed defibrillation uses a synchronization escape period of 500 ms to identify the R-wave for delivering the shock.

- At the first (non-refractory) sensed event, the shock is delivered (Figure 8-4).
- But if the 500 ms escape period times out without a non-refractory event, the shock is delivered asynchronously (Figure 8-5).

The synchronization interval begins at the end of the 300 ms post-charge blanking period, with an effective refractory period of 100 ms. If the AMD senses an event during this refractory period, it starts a new synchronization interval. This subsequent synchronization interval begins with a 120 ms post-sense blanking period and no additional refractory period.

When VF Reconfirmation is active, the shock is synchronized to the first arrhythmic event (page 8-13).

Ventricular Therapies

Ventricular Synchronization

After the charge blanking period, the synchronization interval of 500 ms begins with an effective refractory period of 100 ms.

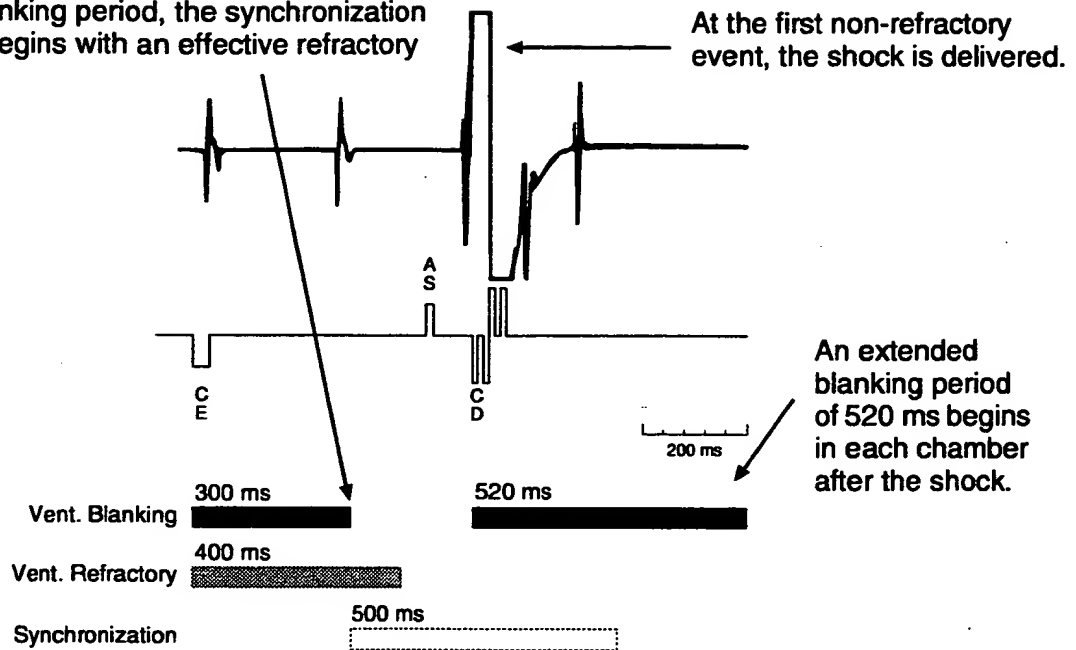


Figure 8-4. V-Defibrillation Synchronized to an Arrhythmic Event

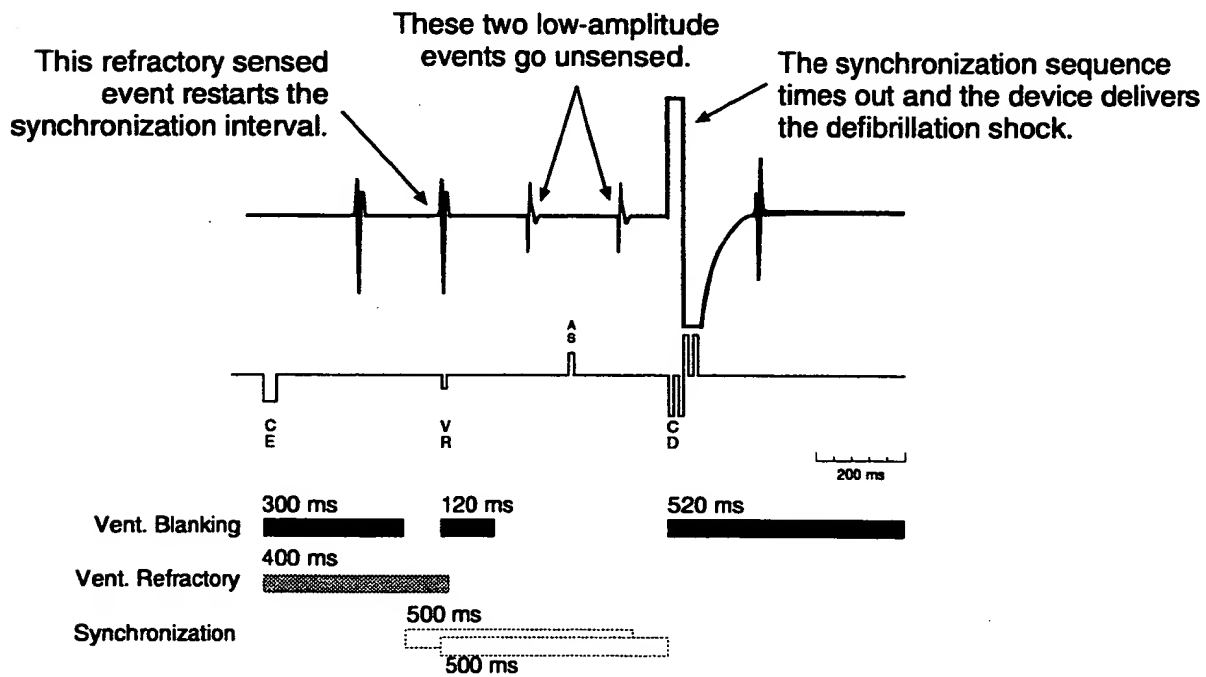


Figure 8-5. V-Defibrillation Delivered After Failing to Synchronize

Reconfirm VF

VF Reconfirmation is automatically used on the first application of the first programmed defibrillation therapy. Subsequent therapies, and re-applications of an aborted first therapy, are always committed.

When VF Reconfirmation is active, the shock is synchronized to the first arrhythmic beat, but it aborts if the VF terminates spontaneously into bradycardia or sinus rhythm.

◆ ***How VF Reconfirmation (Non-Committed Defibrillation) Works***

The first programmed automatic VF therapy is a non-committed therapy, using a reconfirmation “window” to identify an ongoing arrhythmia.

VF Reconfirmation begins after the 300 ms post-charge blanking period. The reconfirmation window lasts for:

- The programmed VT Detection Interval¹ plus 60 ms.

Any normal rhythm event (paced or sensed, with an interval of at least [VTDI plus 60 ms]) restarts a new window, beginning with a post-sense or post-pace blanking period as programmed.

- At the first arrhythmic event (i.e., interval less than [VTDI plus 60 ms]), VF is reconfirmed² and the shock is delivered.
- But the shock aborts if four normal rhythm events occur without reconfirmation of VF.

1. Or VF Detection Interval, if VT Detection is disabled.

2. The preceding event must also have been sensed during reconfirmation. The first event after charge-end, or any event preceded by a paced beat, is not eligible to fulfill VF Reconfirmation.

Ventricular Therapies

Ventricular Synchronization

Bradycardia Pacing During Reconfirmation – Each reconfirmation interval also begins an escape period in the VVI mode when bradycardia pacing is enabled. If the escape period times out, the AMD paces the ventricle and continues to monitor for reconfirmation of VF. The paced beat counts as a normal rhythm event. Any sensed event immediately following the pacing pulse counts as a first arrhythmic event; the shock would be delivered if another arrhythmic event followed it.

Reconfirmation with Pacing Disabled – If bradycardia pacing is programmed OFF, the AMD uses an escape period of 1760 ms for reconfirmation. If this escape period expires without any sensed events, the shock is delivered then.

Ventricular Cardioversion Synchronization

In general, ventricular cardioversion is synchronized to the first non-refractory event (not including the first event after charging ends). The shock aborts if the tachycardia terminates spontaneously. When a Cardioversion Delay is programmed (page 9-20), the pulse is offset from the event. If the tachycardia accelerates, the shock aborts and VF Detection begins.

See page 8-16 for a detailed description of Cardioversion Synchronization.

◆ Programmable Parameters

Cardioversion synchronization is fully automatic and does not require any programming.

CV Delay is not available for automatic ventricular cardioversion therapy.

◆ **How Cardioversion Synchronization Works**

Cardioversion is a non-committed therapy, using a sequence of reconfirmation "windows" to identify an ongoing arrhythmia.

VT Reconfirmation begins **after** the 300 ms post-charge blanking period. The reconfirmation window lasts for

- The programmed VT Detection Interval plus 60 ms.¹

A sensed event during the first window restarts a new window. Any subsequent refractory event restarts a new window. These subsequent windows begin with the 120 ms post-sense blanking period, followed by an effective refractory period of 80 ms.

- At the next (non-refractory) **arrhythmic event**, the tachycardia is reconfirmed² and the shock is delivered.
- If a **reconfirmation window expires** without a ventricular event, the shock aborts at the next event (or escape period timeout) (Figure 8-6).
- The shock aborts if **three events are sensed during refractory periods** (Figure 8-6).

Bradycardia Pacing During Reconfirmation – Each reconfirmation interval begins an escape period in the VVI mode when bradycardia pacing is enabled. If the escape period times out the AMD aborts the cardioversion therapy and paces, using its standard output settings. The escape period is the programmed lower rate interval, up to a maximum of 1760 ms. When bradycardia pacing is programmed OFF, the escape period is 1760 ms.

1. For manual V-Cardioversion, the synchronization window is the bradycardia escape period (1760 ms when pacing is OFF), up to a maximum of 1760 ms.
2. The preceding event must also have been sensed during reconfirmation. The first event after charge-end is not eligible to fulfill VT reconfirmation.

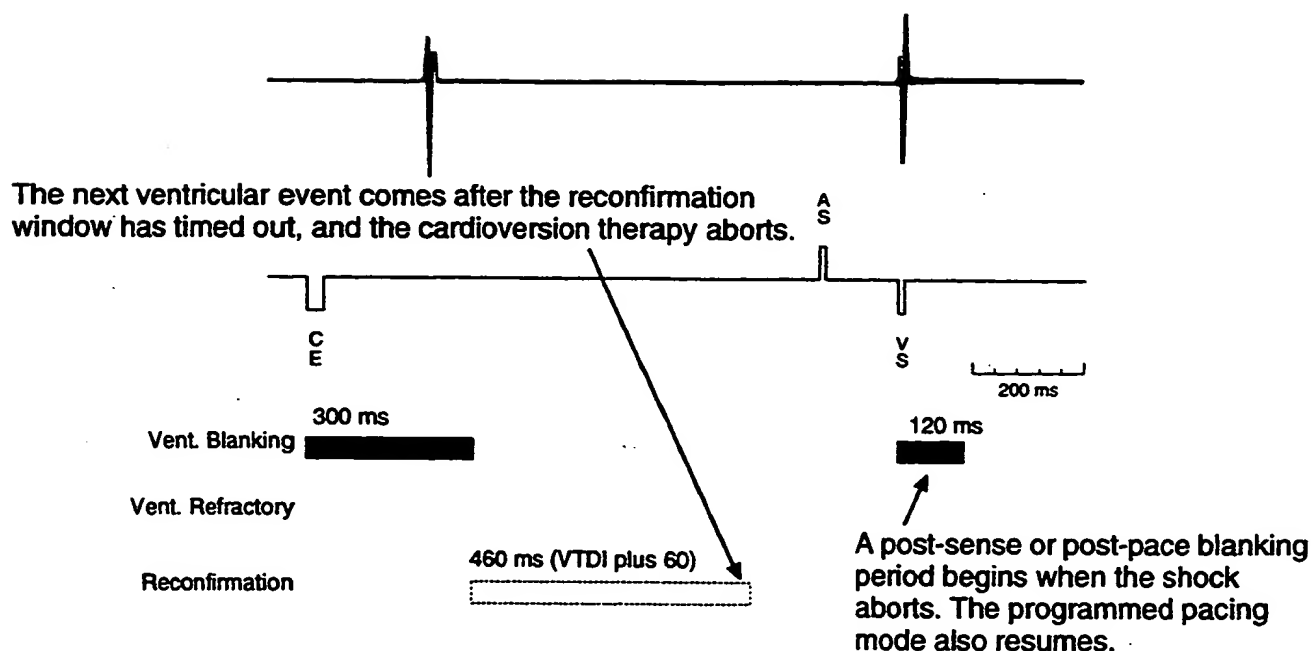


Figure 8-6. Cardioversion Aborts After Failure to Reconfirm

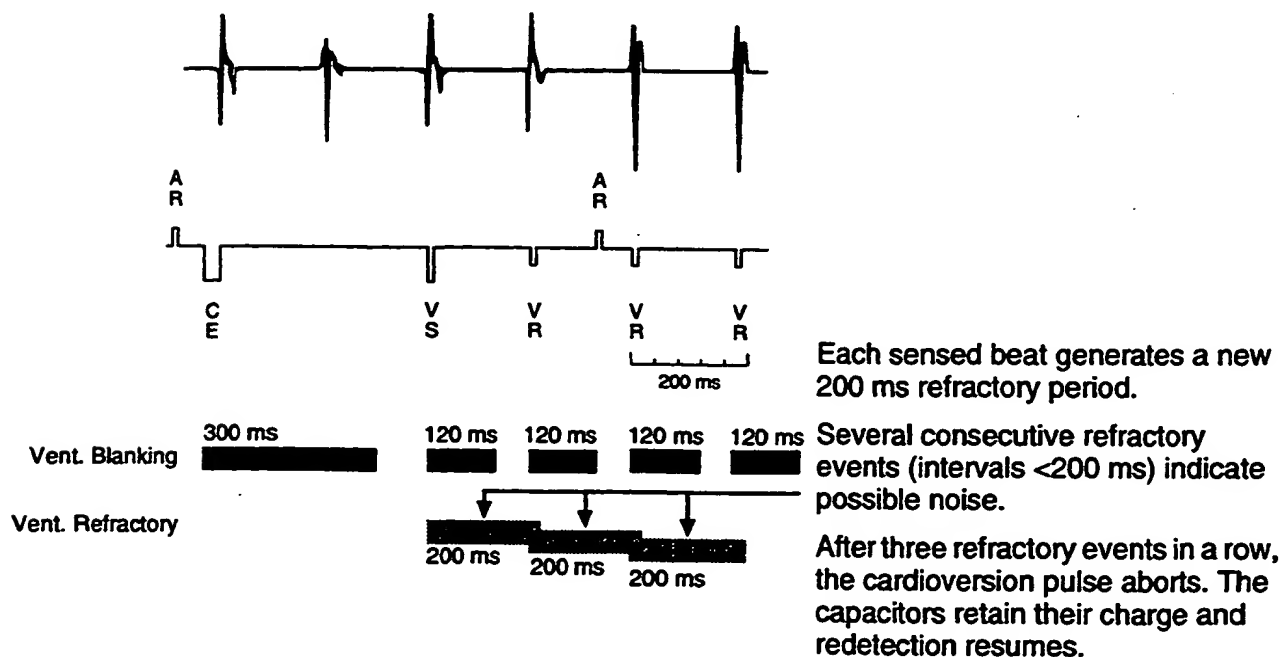


Figure 8-7. Cardioversion Aborts After Three Refractory Beats

Events Following a Ventricular Shock

Following a delivered ventricular defibrillation or cardioversion therapy, the following begin immediately:

- a post-shock blanking period of 520 ms in each chamber.
- one VVI pacing cycle at 50 ppm (escape interval of 1200 ms).¹

After the first ventricular event, the programmed bradycardia pacing mode resumes, using the post-shock output settings (1.5 ms, 6 V—see page 4-9).

The AMD monitors for an outcome (termination or redetection) to the delivered therapy, beginning after the next paced or sensed event. VT Detection is temporarily suspended for 17 events following ventricular defibrillation, to reject any transient tachycardia that may follow the high voltage therapy.

After any therapy delivered manually through the programmer, automatic detection is suspended for as long as the programming head remains over the device, or until Resume Dx is programmed.

After An Aborted Ventricular Shock

Following an aborted ventricular defibrillation or cardioversion therapy, or an aborted charging period, the AMD reverts immediately to its programmed bradycardia pacing settings. The AMD resumes monitoring the cardiac cycle for ventricular arrhythmias, using the programmed redetection NIDs, beginning with the next ventricular event. If the AMD redetects the same arrhythmia after an aborted therapy, it re-attempts to synchronize and deliver the same therapy.

Note: If a high voltage therapy aborts, leaving the energy stored on the capacitors, the delivered energy of a subsequent cardioversion or defibrillation therapy could be higher than the programmed value.

1. If Bradycardia Pacing is programmed OFF, there is no pacing.

Ventricular ATP Therapies

- The pulse width, amplitude, and post-pace blanking period are the same for all ventricular ATP therapies, but are programmed separately from the atrial ATP and the bradycardia pacing values. These values are programmed from the **SHARED** therapies parameter screen.
- The pacing interval is rate adaptive to the average of the last four R-R intervals prior to VT detection or redetection.
- ATP pulses are never delivered at less than the programmed ventricular ATP minimum interval. This minimum pacing interval is the same for all ventricular ATP therapies. If the calculated interval is shorter than the programmed minimum, the pulses are delivered at the programmed minimum interval.
- ATP therapies cannot be delivered as programmed if the tachycardia cycle length is too short. See "Rate Limited Ventricular ATP Therapies" on page 8-28.
- After each ATP sequence, the AMD must redetect the original ventricular arrhythmia before it will deliver the next sequence. If a different arrhythmia is redetected, the therapy is designated unsuccessful and the AMD delivers the next programmed therapy for the current arrhythmia.
- The nominal settings for antitachycardia pacing therapies are based on clinical experience and previous research in antitachycardia pacing. When an antitachycardia pacing therapy is enabled, decide whether to use nominal values or to program new values. Verify the effectiveness of any enabled ATP therapy at the time it is enabled.

V-Burst Pacing

V-Burst therapy consists of a programmable number of sequences of VOO pulses delivered at equal intervals. V-Burst pacing can be programmed as any of the six VT therapies.

See page 8-26 for programming instructions.

◆ **Programmable Parameters**

VT THERAPY STATUS	ON or OFF.
INITIAL # PULSES	Number of pulses in each Burst sequence.
R-S1 INTERVAL	Pacing interval of the first Burst sequence, as a percentage of the pre-therapy R-R average.
INTERVAL DEC	Pacing interval decrement per sequence.
# SEQUENCES	Number of sequences in the therapy.
ANTI-TACHY PACING MINIMUM INTERVAL	Minimum pacing interval for all ventricular ATP therapies.

◆ **How V-Burst Pacing Works**

The first Burst sequence is delivered at the programmed percentage of the current VT cycle length. Each time the VT is redetected after an ineffective sequence, the AMD applies the programmed Burst percentage to the new cycle length, and then subtracts the programmed interval decrement (once per sequence) to calculate the pacing interval for the next Burst sequence.

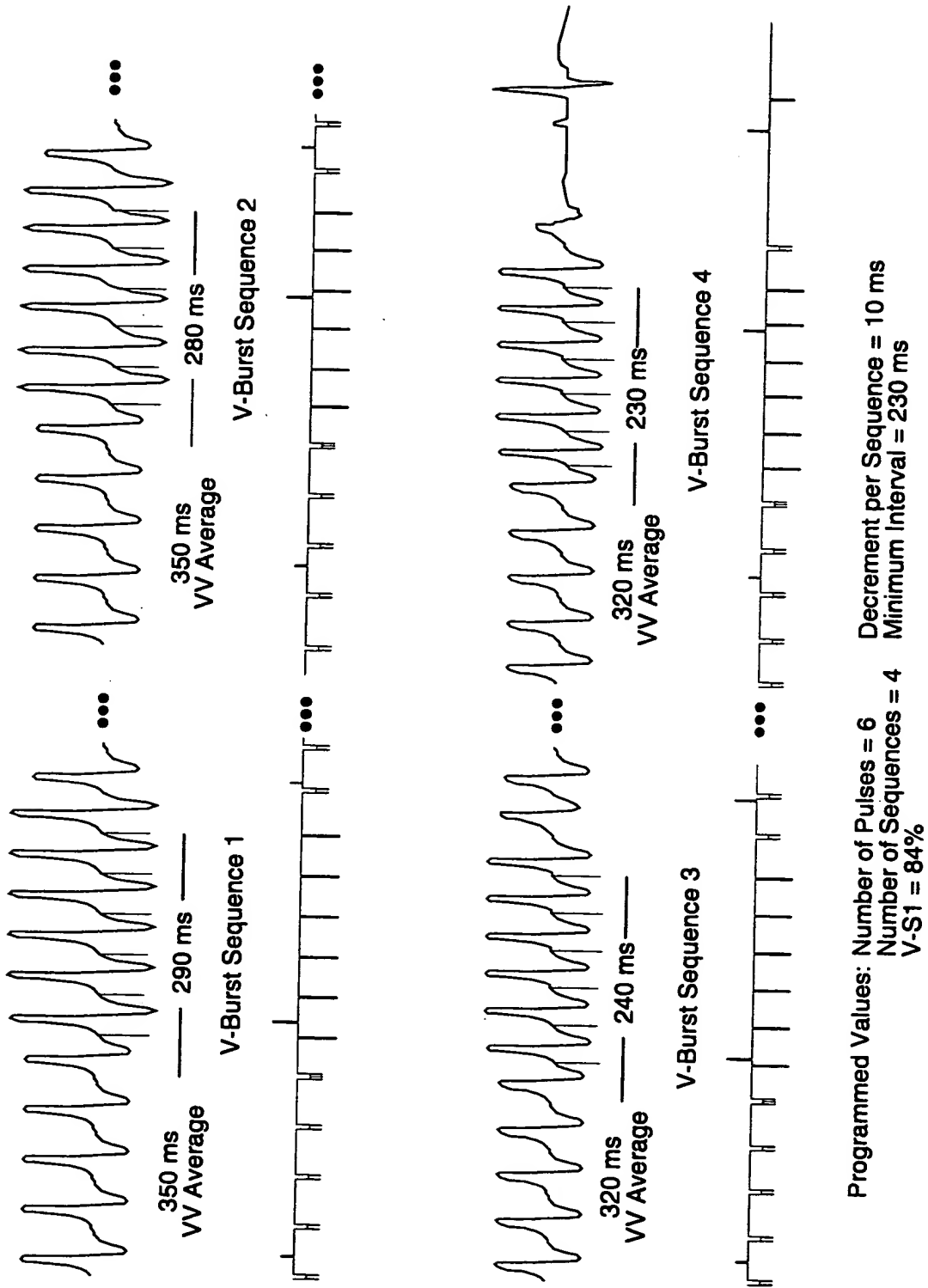


Figure 8-8. V-Burst Pacing Operation

V-Ramp Pacing

V-Ramp therapy consists of a programmable number of sequences of VVI pulses delivered at decreasing intervals. V-Ramp pacing can be selected as any of the six VT therapies.

See page 8-26 for programming instructions.

◆ **Programmable Parameters**

THERAPY STATUS	ON or OFF.
INITIAL # PULSES	Number of pulses in the first V-Ramp sequence.
S1 INTERVAL (%RR)	Pacing interval of the first V-Ramp pulse in each sequence, as a percentage of the current R-R average.
INTERVAL DEC	Pacing interval decrement per pulse for the remaining V-Ramp pulses in each sequence.
# SEQUENCES	Number of sequences in the V-Ramp therapy.
ANTI-TACHY PACING MINIMUM INTERVAL	Minimum pacing interval for all ventricular ATP therapies.

◆ **How V-Ramp Pacing Works**

The first pulse of each V-Ramp sequence is delivered at a selectable percentage of the current VT cycle length. The rest of each sequence is delivered at progressively shorter intervals, based on the programmed interval decrement. Each time the VT is redetected after an ineffective sequence, the AMD applies the programmed Ramp percentage to the new cycle length, and adds one additional pacing pulse per sequence.

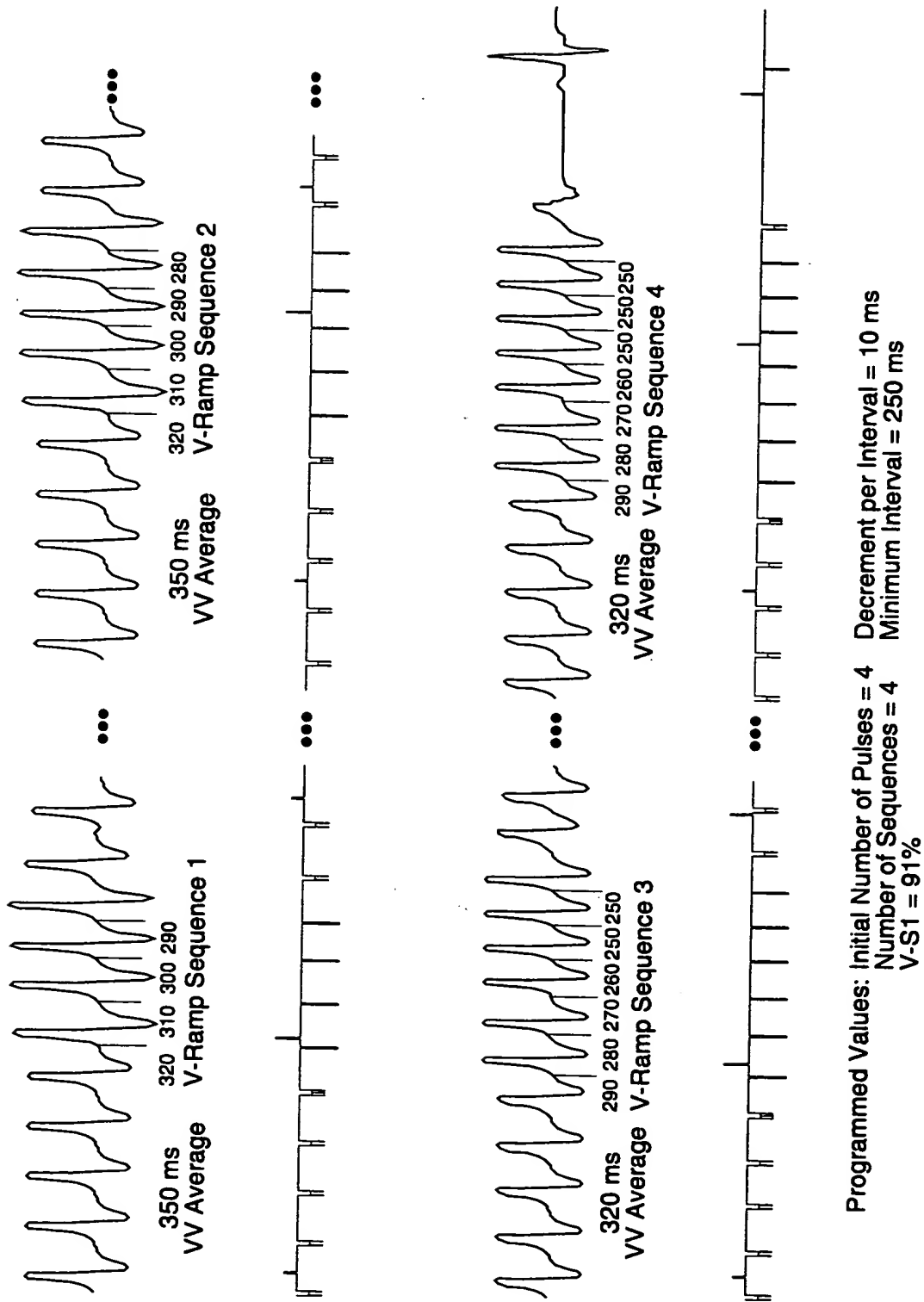


Figure 8-9. V-Ramp Pacing Operation

V-Ramp+ Pacing

V-Ramp+ therapy consists of a programmable number of sequences of VOO pulses delivered at programmable intervals. V-Ramp+ pacing can be selected as any of the six VT therapies.

See page 8-26 for programming instructions.

◆ **Programmable Parameters**

THERAPY STATUS	ON or OFF.
INITIAL # PULSES	Number of pulses in the first Ramp+ sequence.
S1 INTERVAL S1-S2 INTERVAL S2-SN INTERVAL }	Pacing intervals of the first, second, and remaining pulses of the V-Ramp+ sequence, as a percentage of the pre-therapy atrial interval average.
# SEQUENCES	Number of sequences in the Ramp+ therapy.
ANTI-TACHY PACING MINIMUM INTERVAL	Minimum pacing interval for all ventricular ATP therapies.

◆ **How V-Ramp+ Pacing Works**

The first pulse of a V-Ramp+ sequence is delivered at the programmed S1 Interval, timed from the sensed event that fulfills detection; the second pulse is delivered at the S1-S2 percentage; remaining pulses are delivered at the S2-SN percentage. If the VT is redetected, the AMD applies the programmed percentages to the new cycle length to calculate the pacing intervals for the next Ramp+ sequence. Each sequence adds one additional pacing pulse per sequence.

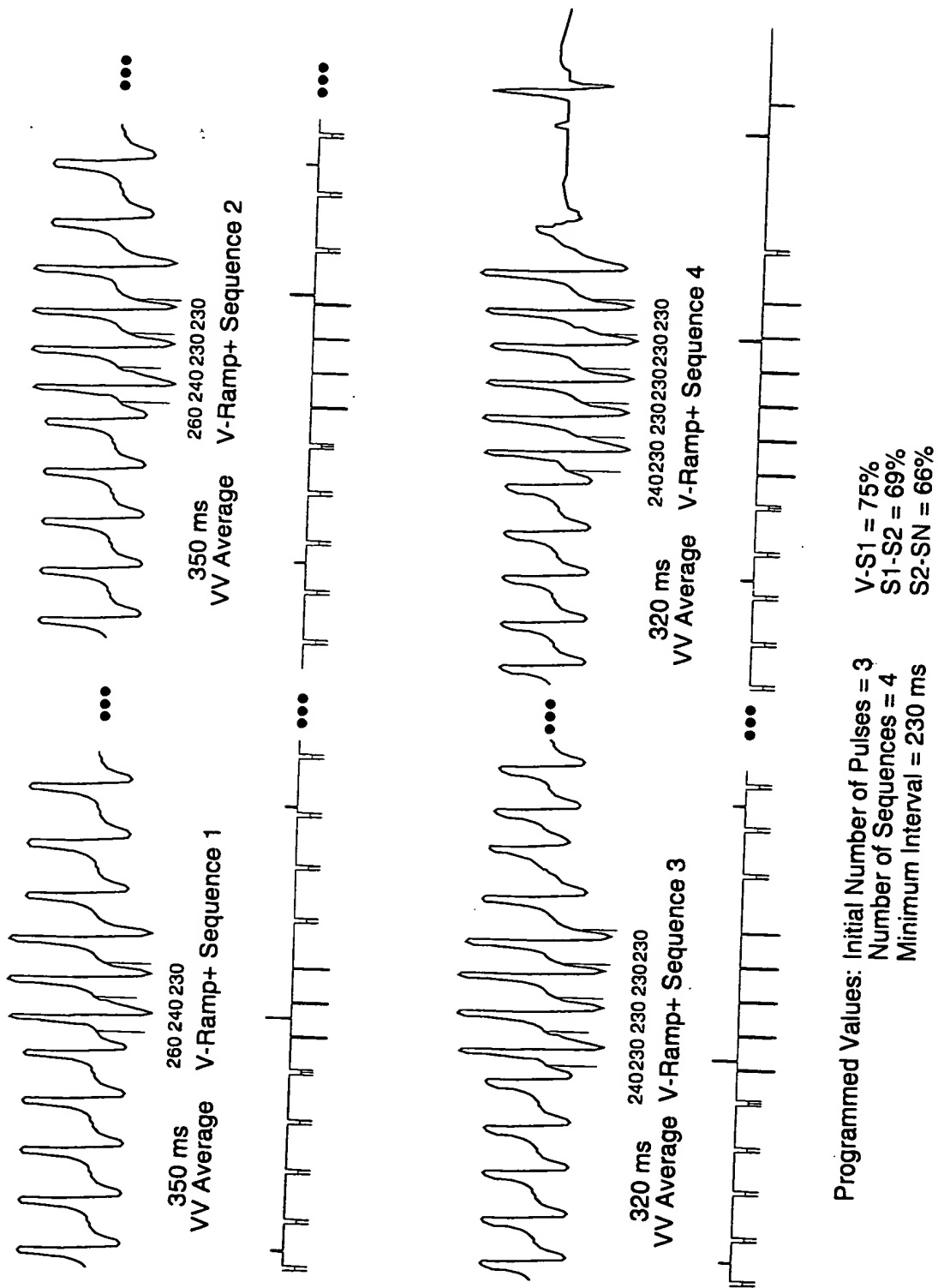


Figure 8-10. V-Ramp+ Pacing Operation

Programming Ventricular Pacing Therapies

How to Program Ventricular ATP Therapies

1. From the **PARAMETERS** menu, select the **THERAPIES** menu option and then the **VT** button.
 - a. Select next to **Therapy Type** and choose appropriate therapy (Burst, Ramp, or Ramp+).
 - b. Select appropriate timing parameters.
2. To program pulse output parameters for all ventricular ATP therapies, select the **SHARED** button.

See Figure 8-11 for VT and Shared programming screens.

Ventricular Therapies

Ventricular ATP Therapies

DATA	TESTS	PARAMETERS	END SESSION	SPECIAL	PRINT
UT THERAPIES: Select parameters and then select PROGRAM.					
VF	VT	AF/AT	PATIENT	SHARED	SHOW PRESENT
	1	2	3	4	5
UT Therapy Status:	ON	ON	ON	ON	ON
Therapy Type:	BURST	RAMP	RAMP+	CV	CV
Initial # Pulses:	6	8	3		
S1 Interval-(%RR):	84	91	75		
S1S2(RAMP+)-(%RR):			69		
S2SN(RAMP+)-(%RR):			66		
Interval Dec (ms):	18	18			
# Sequences:	5	5			
Energy(J):				27	27
Pathway:				CAN-BUC	CAN-BUC
					27
					CAN-BUC
Anti-Tachy Pacing Minimum Interval (ms):					280

Automatic
Ventricular Pacing
Parameters
(circled)

DATA	TESTS	PARAMETERS	END SESSION	SPECIAL	PRINT
SHARED THERAPY PARAMETERS: Select parameters and then select PROGRAM.					
VF	VT	AF/AT	PATIENT	SHARED	
SHARED ATRIAL THERAPY PARAMETERS:					
Pulse Width(ms):	1.5	Tilt(CX):	50		
Amplitude(V):	8	ADefib V. Refract:	400		
Pace Blank(ms):	250				
Min. A-A Interval (ms):	150				
SHARED VENTRICULAR THERAPY PARAMETERS:					
Pulse Width(ms):	1.5	Tilt(CX):	50		
Amplitude(V):	8				
Pace Blank(ms):	250				

Figure 8-11. VT and Shared Therapy Screens (partial)

Cancelled Ventricular ATP Therapies

Rate Limited Ventricular ATP Therapies

Ventricular antitachycardia pacing pulses are never delivered at less than the programmed minimum pacing interval. If the average tachycardia cycle length is too short, the AMD uses the following two algorithms:

- If the detected VT cycle length is less than or equal to the programmed minimum pacing interval, the AMD cannot deliver any pacing therapy that will overdrive the intrinsic rate. The AMD cancels the rest of that pacing therapy and skips to the next programmed cardioversion therapy. If no cardioversion therapy is programmed, no therapy is delivered.
- If all the intervals of a ventricular ATP therapy sequence are delivered at the minimum interval, the therapy is fully rate limited. The AMD will not deliver any more sequences of that pacing therapy if the tachycardia is redetected at the same or faster cycle length; instead it skips to the next programmed ventricular therapy.

Tachycardia Accelerated by a Ventricular ATP Therapy

After delivering each ATP therapy sequence, the AMD monitors for an outcome. If the tachycardia accelerates to VF, or if VT Acceleration occurs, the remaining sequences of the pacing therapy are not delivered. Instead, the AMD delivers the next programmed therapy for the current arrhythmia.

EP Study

9

The AMD system provides you with non-invasive Electrophysiologic Study (EPS) capabilities via the **TESTS** menu options. EP Study features help you to confirm the inducibility of the patient's clinical arrhythmia(s), and to evaluate the effectiveness of AMD therapies. During follow-up sessions, EP Studies can help you to reevaluate the treatment regimen as changes in the patient's condition or drug therapy occur.

Overview of EP Studies 9-2

A/V-PES Induction 9-6

A/V-50 Hz Burst Induction 9-8

V T-Shock™ Induction 9-10

***A-50 Hz Burst Manual
Therapy 9-12***

A-Burst+ Manual Therapy 9-14

***A/V-Defibrillation Manual
Therapy 9-16***

A/V-Ramp Manual Therapy 9-18

***V-Cardioversion Manual
Therapy 9-20***

V-Burst Manual Therapy 9-22

V-Ramp+ Manual Therapy 9-24

Overview of EP Studies



Warning: Perform EP Study functions only under careful patient monitoring and control. Keep an external defibrillator immediately available and on standby during EP Study operations. An induced ventricular tachycardia may degenerate to ventricular fibrillation.

The EP Study features provide induction protocols and manual therapy options. The manual therapies operate in the same way as the AMD's automatic therapies, but their parameters are programmed independently from the automatic therapy parameters. You can also allow the automatic detection and therapy features to detect and terminate the induced arrhythmias.

Table 9-1. EP Study Operations

INDUCTIONS

- A/V- Programmed Electrical Stimulation (PES)
- A/V- 50 Hz Burst
- V- T-Shock™

MANUAL THERAPIES

- A- 50 Hz Burst pacing
 - A- Burst+ pacing
 - A/V- Defibrillation
 - A/V- Ramp pacing
 - V- Cardioversion
 - V- Burst pacing
 - V- Ramp+ pacing
-

System Operation During EP Studies

EP Study inductions can be performed with automatic detection either active or suspended. Delivering a manual therapy suspends the AMD's detection features. You must press the on-screen **RESUME Dx** button, or remove the programming head from the AMD, to resume detection. If the programming head is removed during an EP Study operation, the AMD completes the operation and then reverts to its permanently programmed values.

The **PROGRAM** and **INTERROGATE** buttons on the programming head are disabled during EP Study inductions. Use the on-screen **DELIVER** button to deliver an induction.

Device Status Line – The Device Status Line informs you of the status of a manual therapy in progress if telemetry exists between the AMD and programmer. During a manual therapy (except during high voltage capacitor charging), the Device Status Line displays the message **MANUAL OPERATION IN PROGRESS**. During charging for a manual therapy, the Device Status Line displays the message **MANUAL OPERATION CHARGING**.

Pre-Induction Self-Check – Before delivering the first induction protocol, the AMD system checks to verify that it is programmed to detect and treat an induced arrhythmia. If the AMD's detection or therapy features are not programmed appropriately, a warning message appears on screen.

Bradycardia Pacing During Atrial Inductions – Backup ventricular pacing is not available during atrial pace inductions.

Temporary Parameter Values

EP Study functions use *test values* that do not change the AMD's permanently programmed parameters.

Test values are not in effect until you begin the induction or therapy by selecting **DELIVER**. After the induction or therapy is complete, the AMD reverts to its permanently programmed values.

Selecting Values – You select test values for EP Study functions in the same way as during permanent programming, with the following exceptions:

- When you select a value, the programmer does not display a dashed rectangle around the parameter name and value field.
- The Present Indicator (►) appearing in the window indicates the current test value, not the permanent programmed value.
- The programmer displays increment/decrement buttons, used to change the test values:



As the value changes, the programmer emits a beep for every increment or decrement. To scan the range of values, press and hold the pen against the increment/decrement button.

Aborting an EP Induction or Therapy

As a safety precaution, the programmer also displays an **ABORT** button which immediately terminates any induction, manual therapy, or charge in progress. EP Study functions terminate either immediately after delivery of stimulation, or with the release of the on-screen **DELIVER** button or the **PROGRAM** button on the programming head.

A/V-PES Induction

Programmed Electrical Stimulation (PES) delivers sequences of premature stimuli to induce AF/AT or VT. Each PES sequence consists of a selectable number of paced or sensed beats in AAI/VVI mode (labeled S1), followed by up to three premature AOO/VOO paced beats, labeled S2, S3, and S4. The pulse amplitude and pulse width are programmed in common for all the stimuli in an induction.

◆ **Programmable Parameters**

Chamber	Atrium or ventricle.
#S1	Number of pulses in the pulse train.
S1S1 (ms)	Pacing interval of the pulse train.
S1S2 (ms)	Pacing interval of the first premature pulse (S2).
S2S3 (ms)	Pacing interval of the second premature pulse (S3).
S3S4 (ms)	Pacing interval of the third premature pulse (S4).
Amplitude (V)	Pulse amplitude of all PES pulses.
Pulse Width (ms)	Pulse width of all PES pulses.

◆ **How To Deliver a PES Induction**



Warning: Keep an external defibrillator immediately available and on standby.

1. From the **TESTS** menu, select **EP STUDY**. The programmer displays the EP Study screen.
2. From the EP Study screen, select **INDUCTIONS** and then **PES** (partial screen shown below).
3. Select appropriate chamber.

4. Accept the parameter values shown on the screen, or select new values.
 - a. To change the number of pulses (#S1) or any of the pacing intervals, select a new value by pressing or .
 - b. To disable S4, touch the pen to . Confirm that the interval value changes to OFF.
 - c. To disable S3 and S4, touch the pen to . Confirm that the interval values change to OFF.
 - d. To disable S2, S3, and S4, touch the pen to . Confirm that the interval values change to OFF.
 - e. Select **Amplitude** and **Pulse Width** values.
5. Check the Device Status Line to confirm that the AMD is programmed correctly for treatment of the induced arrhythmia.
 - a. If you intend to allow the AMD to detect and treat the arrhythmia, confirm that automatic detection and therapies are programmed ON and are not suspended.
 - b. If you intend to deliver a manual therapy, confirm that automatic detection is suspended.
6. Position the programming head and select .

PES Induction
Parameters
(circled)

DATA	TESTS	PARAMETERS	END SESSION	SPECIAL	PRINT
PES INDUCTION: Select DELIVER to start PES sequence.					
INDUCTIONS			MANUAL THERAPIES		
#S1	S1S1(ms)	S1S2(ms)	S2S3(ms)	S3S4(ms)	Amplitude(V): 6
8	600	400	400	400	Pulse Width(ms): 1.5
▲ ▼	▲ ▼	▲ ▼	▲ ▼	▲ ▼	Chamber:
					<input type="button" value="ATRIUM"/> <input type="button" value="VENTRICLE"/>

A/V-50 Hz Burst Induction

50 Hz Burst induction delivers a train of pacing pulses to induce AF/AT or VF. The pulse amplitude and pulse width are selectable; the cycle length is fixed at 20 ms.

◆ **Programmable Parameters**

Chamber	Atrium or ventricle.
Amplitude (V)	Pulse amplitude of 50 Hz Burst pulses.
Pulse Width (ms)	Pulse width of 50 Hz Burst pulses.

◆ **Operating Considerations**

Marker supplement data (Device Status Line) and Marker Channel annotations may not be available during the induction. The programmer displays a Marker Buffer Full (ER) symbol if necessary, which is normal and should be expected during a 50 Hz Burst.

◆ **How to Deliver a 50 Hz Burst Induction**



Warning: Keep an external defibrillator immediately available and on standby.

1. From the **TESTS** menu, select **EP STUDY**. The programmer displays the EP Study screen.
2. From the EP Study screen, select **INDUCTIONS** and then **50 Hz BURST** (partial screen shown below).
3. Select appropriate chamber.
4. Accept the **Amplitude** and **Pulse Width** values shown on the screen, or select new values.
5. Check the Device Status Line to confirm that the AMD is programmed correctly for treatment of the induced arrhythmia.
 - a. If you intend to allow the AMD to detect and treat the arrhythmia, confirm that automatic detection and therapies are programmed ON and are not suspended.
 - b. If you intend to deliver a manual therapy, confirm that automatic detection is suspended.
6. Position the programming head and *press and hold* the **DELIVER** button to deliver the 50 Hz Burst. The burst continues until you release the button, or after about 10 to 12 seconds.

50 Hz Burst Induction
Parameters
(circled)

DATA	TESTS	PARAMETERS	END SESSION	SPECIAL	PRINT
50 Hz BURST INDUCTION: Press and hold DELIVER to start 50 Hz induction.					
INDUCTIONS		MANUAL THERAPIES		Amplitude(V): 6	
Interval(ms)		20		Pulse Width(ms): 1.5	
				Chamber:	
				<input type="radio"/> ATRIUM <input type="radio"/> VENTRICLE	

V T-Shock™ Induction

To induce VF, ventricular T-Shock™ induction delivers two to eight VOO pacing stimuli followed, after a programmable delay interval, by a programmable shock. The intent is to deliver the shock during the ventricle's vulnerable period to induce VF.

As a safety measure, the programmer displays the **DELIVER** button only after you have enabled T-Shock™ induction with the **ON** button. After delivering a shock or exiting the screen, you must re-enable T-Shock™ induction before delivering again.

◆ Programmable Parameters

#S1	Number of pulses in the pulse train.
S1S1 (ms)	Pacing interval of the pulse train.
Delay (ms)	Interval between the final pulse and the shock.
Energy (J)	Stored energy (in joules) of the shock stimulus.
Waveform	Waveform type (biphasic or monophasic).
Pathway	Delivery pathway.
ENABLE	Enables/disables T-Shock™ induction.

◆ Operating Considerations

Fixed Parameters – The pulse width of the VOO pulses is fixed at 1.5 ms. The pulse amplitude of the VOO pulses is fixed at 6 V.

Scanning the T-Wave – If the nominal values do not induce VF, alternately increase and decrease the **DELAY** in increments from the initial value (e.g., 330, 290, 350, 270, . . .) to “scan” the T-wave. If this fails, increase the **ENERGY** to two joules and repeat the scan.

◆ **How to Deliver a T-Shock™ Induction**



Warning: Keep an external defibrillator immediately available and on standby.

1. From the **TESTS** menu, select **EP STUDY**. The programmer displays the EP Study screen.
2. From the EP Study screen, select **INDUCTIONS** and then **V T-WAVE SHOCK** (partial screen shown below).
3. Accept the #S1, S1S1, Delay and Energy parameter values shown on the screen, or select new values by pressing **^** or **v**. Select **Waveform** and **Pathway** values.
4. Set **ENABLE** to **ON**.
5. Check the Device Status Line to confirm that the AMD is programmed correctly for treatment of the induced VF.
 - a. If you intend to allow the AMD to detect and treat the VF, confirm that VF Detection and automatic therapies are programmed ON and are not suspended.
 - b. If you intend to deliver a manual therapy, confirm that automatic detection is suspended.
6. Position the programming head and select **DELIVER**.

V T-Shock Induction
Parameters
(circled)

DATA		TESTS		PARAMETERS		END SESSION		SPECIAL		PRINT	
V T-WAVE SHOCK INDUCTION: Select DELIVER to start T-Wave Shock sequence.											
INDUCTIONS				MANUAL THERAPIES							
#S1		S1S1(ms)		Delay(ms)		Energy(J)					
(8)		400		310		0.5					
v		^		v		^		v		^	
Waveform: MONO				Pathway: CATH-LOC							
ENABLE											
ON				OFF							

A-50 Hz Burst Manual Therapy

50 Hz Burst manual therapy delivers a train of pacing pulses of programmable duration. The duration, pulse amplitude and pulse width are selectable; the cycle length is fixed at 20 ms.

◆ **Programmable Parameters**

Duration (sec)	Duration of 50 Hz Burst.
Amplitude (V)	Pulse amplitude of 50 Hz Burst pulses.
Pulse Width (ms)	Pulse width of 50 Hz Burst pulses.

◆ **Operating Considerations**

Marker supplement data (Device Status Line) and Marker Channel annotations may not be available during the induction. The programmer displays a Marker Buffer Full (ER) symbol if necessary, which is normal and should be expected during a 50 Hz Burst.

◆ **How to Deliver an A-50 Hz Burst Manual Therapy**



Warning: Keep an external defibrillator immediately available and on standby.

1. From the **TESTS** menu, select **EP STUDY**. The programmer displays the EP Study screen.
2. From the EP Study screen, select **MANUAL THERAPIES** and then **A 50 Hz BURST** (partial screen shown below).
3. Accept the **Duration (sec)** value shown on the screen, or select a new value by pressing **^** or **v**. Select **Amplitude (V)** and **Pulse Width (ms)** values.
4. Position the programming head and select **DELIVER**.

A-50 Hz Burst Manual
Therapy Parameters
(circled)

DATA	TESTS	PARAMETERS	END SESSION	SPECIAL	PRINT
ATRIAL 50 HZ MANUAL THERAPY: Select DELIVER to start burst.					
INDUCTIONS		MANUAL THERAPIES		Amplitude(V): 6	
Interval(ms) 20		Duration(sec) 2.8		Pulse Width(ms): 1.5	
		^ v			

A-Burst+ Manual Therapy

Manual A-Burst+ Therapy delivers one sequence of A-Burst+ antitachycardia pacing therapy. The timing and pacing modes of the A-Burst+ sequence are detailed in "A-Burst+ Pacing" on page 7-22.

◆ **Programmable Parameters**

# S1	Number of pulses in the sequence.
A-S1 (%AA)	Pacing interval of the first pulse, as a percentage of the pre-therapy interval average.
S1S2 (%AA)	Pacing interval of the second pulse, as a percentage of the pre-therapy interval average.
S2S3 (%AA)	Pacing interval of the remaining pulses, as a percentage of the pre-therapy interval average.
Minimum Interval (ms)	Minimum pacing interval for the sequence. Once this interval is reached, any remaining pulses are delivered at this interval.
Amplitude (V)	Pulse amplitude of all pulses.
Pulse Width (ms)	Pulse width of all pulses.

◆ **Operating Considerations**

You can deliver a manual therapy without having to abort an induction or another manual therapy that may be in progress.

Delivering a manual therapy suspends the AMD's detection features. You must press the on-screen **RESUME Dx** button or remove the programming head from the AMD to resume detection.

Following delivery of the manual therapy, the AMD reverts to operation according to its programmed parameter values.

◆ **How to Deliver an A-Burst+ Manual Therapy**



Warning: Keep an external defibrillator immediately available and on standby.

1. From the **TESTS** menu, select **EP STUDY**. The programmer displays the EP Study screen.
2. From the EP Study screen, select **MANUAL THERAPIES** and then **A BURST+** (partial screen shown below).
3. Accept the # Pulses, A-S1, S1S2, and S2S3 values shown on the screen, or select new values by pressing **^** or **v**. Select Minimum Interval (ms), Amplitude (V), and Pulse Width (ms) values.
4. Position the programming head and select **DELIVER**.

A-Burst+ Manual Therapy
Parameters
(circled)

DATA	TESTS	PARAMETERS	END SESSION	SPECIAL	PRINT
ATRIAL BURST+ MANUAL THERAPY: Select DELIVER to start Burst+ sequence.					
INDUCTIONS		MANUAL THERAPIES		Minimum Interval(ms): 150	
#S1	A-S1(ZAA)	S1S2(ZAA)	S2S3(ZAA)	Amplitude(V): 6	
6	91	84	78	Pulse Width(ms): 1.5	
^ v	^ v	^ v	^ v		

A/V-Defibrillation Manual Therapy

Manual Defibrillation Therapy charges the AMD and delivers an atrial or ventricular shock.

Atrial defibrillation is synchronized to a sensed event outside of the ventricular vulnerable period, as described in "Atrial Defibrillation Synchronization" on page 7-14. Ventricular defibrillation is synchronized to a sensed R-wave if possible, as described in "Ventricular Defibrillation Synchronization" on page 8-11.

◆ **Programmable Parameters**

Chamber	Atrium or ventricle.
Energy (J)	Energy level (in joules) of the defibrillation shock.
Pathway	Delivery pathway.
Tilt (%)	Tilt of defibrillation pulse.
Synchronization (Atrial defib. only)	Synchronization scheme for atrial defibrillation pulse.

◆ **Operating Considerations**

You can deliver a manual therapy without having to abort an induction or another manual therapy that may be in progress.

Delivering a manual therapy suspends the AMD's detection features. You must press the on-screen **RESUME Dx** button or remove the programming head from the AMD to resume detection.

Following delivery of the manual therapy, the AMD reverts to operation according to its programmed parameter values.

◆ **How to Deliver a Defibrillation Manual Therapy**



Warning: Keep an external defibrillator immediately available and on standby.

1. From the **TESTS** menu, select **EP STUDY**. The programmer displays the EP Study screen.
2. From the EP Study screen, select **MANUAL THERAPIES** and then **DEFIBRILLATION** (partial screen shown below).
3. Select appropriate chamber.
4. Accept the **Energy (J)** value shown on the screen, or select a new value by pressing or . Select **Pathway**, **Tilt (%)**, and **Synchronization** (A-Defib. only) values.
5. Position the programming head and select **DELIVER**.

Defibrillation Manual
 Therapy Parameters
 (circled)

DATA	TESTS	PARAMETERS	END SESSION	SPECIAL	PRINT
DEFIBRILLATION MANUAL THERAPY: Select DELIVER to start Defibrillation.					
INDUCTIONS		MANUAL THERAPIES		Pathway: CAN+S1>BV Tilt(X): 50 Synchronization: V ONLY	
Energy(J) (27) 		Chamber: <div style="display: flex; justify-content: space-around;"> <div style="border: 1px solid black; padding: 2px 10px;">ATRIUM</div> <div style="border: 1px solid black; padding: 2px 10px;">VENTRICLE</div> </div>			

A/V-Ramp Manual Therapy

Manual A/V-Ramp Therapy delivers one sequence of atrial or ventricular Ramp antitachycardia pacing therapy. The timing and pacing modes of the Ramp sequences are detailed in “A-Ramp Pacing” on page 7-24 and “V-Ramp Pacing” on page 8-22.

◆ **Programmable Parameters**

Chamber	Atrium or ventricle.
# Pulses	Number of pulses in the Ramp sequence.
%RR Interval	Pacing interval of the first Ramp pulse, as a percentage of the pre-therapy interval average.
Dec/Pulse (ms)	Decrement per pulse for the remaining Ramp pulses.
Minimum Interval (ms)	Minimum pacing interval for the Ramp sequence. Once this interval is reached, any remaining pulses are delivered at this interval.
Amplitude (V)	Pulse amplitude of all pulses.
Pulse Width (ms)	Pulse width of all pulses.

◆ **Operating Considerations**

You can deliver a manual therapy without having to abort an induction or another manual therapy that may be in progress.

Delivering a manual therapy suspends the AMD's detection features. You must press the on-screen **RESUME Dx** button or remove the programming head from the AMD to resume detection.

Following delivery of the manual therapy, the AMD reverts to operation according to its programmed parameter values.

◆ **How to Deliver a Ramp Manual Therapy**



Warning: Keep an external defibrillator immediately available and on standby.

1. From the **TESTS** menu, select **EP STUDY**. The programmer displays the EP Study screen.
2. From the EP Study screen, select **MANUAL THERAPIES** and then **RAMP** (partial screen shown below).
3. Select appropriate chamber.
4. Accept the # Pulses, %RR Interval, and Dec/Pulse (ms) values shown on the screen, or select new values by pressing **^** or **v**. Select Minimum Interval (ms), Amplitude (V), and Pulse Width (ms) values.
5. Position the programming head and select **DELIVER**.

Ramp Manual Therapy
Parameters
(circled)

DATA	TESTS	PARAMETERS	END SESSION	SPECIAL	PRINT
RAMP MANUAL THERAPY: Select DELIVER to start Ramp sequence.					
INDUCTIONS		MANUAL THERAPIES		Minimum Interval(ms): 200	
# Pulses	% Interval	Dec/Pulse(ms)		Amplitude(V): 6	
6	97	18		Pulse Width(ms): 1.5	
<input type="button" value="^"/> <input type="button" value="v"/>		<input type="button" value="v"/> <input type="button" value="^"/> <input type="button" value="v"/>		Chamber:	
				<input type="button" value="ATRILUM"/> <input type="button" value="VENTRICLE"/>	

V-Cardioversion Manual Therapy

Manual V-Cardioversion Therapy charges the AMD, reconfirms the ventricular tachycardia, and delivers one non-committed shock. The shock must synchronize to a sensed R-wave or it aborts, as described in "Ventricular Cardioversion Synchronization" on page 8-15.

You can program a cardioversion delay to tailor the timing of the shock. The cardioversion pulse is delayed by the programmed CV Delay value after the R-wave that fulfills the reconfirmation sequence (see page 8-16).

◆ **Programmable Parameters**

Energy (J)	Energy level (in joules) of cardioversion shock.
CV Delay (ms)	Cardioversion delay (in milliseconds).

◆ **Operating Considerations**

You can deliver a manual therapy without having to abort an induction or another manual therapy that may be in progress.

Delivering a manual therapy suspends the AMD's detection features. You must press the on-screen **RESUME Dx** button or remove the programming head from the AMD to resume detection.

Following delivery of the manual therapy, the AMD reverts to operation according to its programmed parameter values.

◆ **How to Deliver a V-Cardioversion Manual Therapy**



Warning: Keep an external defibrillator immediately available and on standby.

1. From the **TESTS** menu, select **EP STUDY**. The programmer displays the EP Study screen.
2. From the EP Study screen, select **MANUAL THERAPIES** and then **V CARDIOVERSION** (partial screen shown below).
3. Accept the **Energy (J)** and **CV Delay (ms)** values shown on the screen, or select new values by pressing **^** or **v**. Select **Pathway** and **Tilt (%)** values.
4. Position the programming head and select **DELIVER**.

V-Cardioversion Manual
 Therapy Parameters
 (circled)

DATA	TESTS	PARAMETERS	END SESSION	SPECIAL	PRINT
VENT. CARDIOVERSION MANUAL THERAPY: Select DELIVER to start Cardioversion.					
INDUCTIONS		MANUAL THERAPIES		Pathway: CAN-BUC	
Energy(J)		CV Delay(ms)		Tilt(%): 50	
(27)		(8)			
v		^			

V-Burst Manual Therapy

Manual V-Burst Therapy delivers one sequence of ventricular burst antitachycardia pacing therapy. The timing and pacing modes of the Burst sequence are detailed in "V-Burst Pacing" on page 8-20.

◆ **Programmable Parameters**

# Pulses	Number of pulses in the Burst sequence.
%RR Interval	Pacing interval of the Burst sequence, as a percentage of the pre-therapy interval average.
Minimum Interval (ms)	Minimum pacing interval for the Burst sequence. Once this interval is reached, any remaining pulses are delivered at this interval.
Amplitude (V)	Pulse amplitude of all pulses.
Pulse Width (ms)	Pulse width of all pulses.

◆ **Operating Considerations**

You can deliver a manual therapy without having to abort an induction or another manual therapy that may be in progress.

Delivering a manual therapy suspends the AMD's detection features. You must press the on-screen **RESUME Dx** button or remove the programming head from the AMD to resume detection.

Following delivery of the manual therapy, the AMD reverts to operation according to its programmed parameter values.

◆ **How to Deliver a V-Burst Manual Therapy**



Warning: Keep an external defibrillator immediately available and on standby.

1. From the **TESTS** menu, select **EP STUDY**. The programmer displays the EP Study screen.
2. From the EP Study screen, select **MANUAL THERAPIES** and then **V BURST** (partial screen shown below).
3. Accept the # Pulses and %RR Interval values shown on the screen, or select new values by pressing **^** or **v**. Select Minimum Interval (ms), Amplitude (V), and Pulse Width (ms) values.
4. Position the programming head and select **DELIVER**.

V-Burst Manual Therapy
Parameters
(circled)

DATA	TESTS	PARAMETERS	END SESSION	SPECIAL	PRINT
VENT. BURST MANUAL THERAPY: Select DELIVER to start Burst sequence.					
INDUCTIONS		MANUAL THERAPIES		Minimum Interval(ms): 200	
# Pulses		%RR Interval		Amplitude(V): 6	
6		84		Pulse Width(ms): 1.5	
^ v		^ v			

V-Ramp+ Manual Therapy

Manual V-Ramp+ Therapy delivers one sequence of ventricular Ramp+ antitachycardia pacing therapy. The timing and pacing modes of the Ramp+ sequence are detailed in "V-Ramp+ Pacing" on page 8-24.

◆ Programmable Parameters

# Pulses	Number of pulses in the sequence.
R-S1 (%RR)	Pacing interval of the first pulse, as a percentage of the pre-therapy interval average.
S1S2 (%RR)	Pacing interval of the second pulse, as a percentage of the pre-therapy interval average.
S2SN (%RR)	Pacing interval of the remaining pulses, as a percentage of the pre-therapy interval average.
Minimum Interval (ms)	Minimum pacing interval for the sequence. Once this interval is reached, any remaining pulses are delivered at this interval.
Amplitude (V)	Pulse amplitude of all pulses.
Pulse Width (ms)	Pulse width of all pulses.

◆ Operating Considerations

You can deliver a manual therapy without having to abort an induction or another manual therapy that may be in progress.

Delivering a manual therapy suspends the AMD's detection features. You must press the on-screen **RESUME Dx** button or remove the programming head from the AMD to resume detection.

Following delivery of the manual therapy, the AMD reverts to operation according to its programmed parameter values.

◆ **How to Deliver a V-Ramp+ Manual Therapy**



Warning: Keep an external defibrillator immediately available and on standby.

1. From the **TESTS** menu, select **EP STUDY**. The programmer displays the EP Study screen.
2. From the EP Study screen, select **MANUAL THERAPIES** and then **RAMP+** (partial screen shown below).
3. Accept the # Pulses, R-S1, S1S2, and S2SN values shown on the screen, or select new values by pressing **^** or **v**. Select Minimum Interval (ms), Amplitude (V), and Pulse Width (ms) values.
4. Position the programming head and select **DELIVER**.

V-Ramp+ Manual Therapy
Parameters
(circled)

DATA	TESTS	PARAMETERS	END SESSION	SPECIAL	PRINT
VENT. RAMP+ MANUAL THERAPY: Select DELIVER to start Ramp+ sequence.					
INDUCTIONS		MANUAL THERAPIES		Minimum Interval(ms): 200	
# Pulses	R-S1(ZRR)	S1S2(ZRR)	S2SN(ZRR)	Amplitude(V): 6	
3	75	69	66	Pulse Width(ms): 1.5	
^ v	^ v	^ v	^ v		

System Tests

10

The programmer provides you with system test capabilities via the **TESTS** menu options. These test features enable you to assess the status of the AMD system. The AMD also tests the system with several automatic measurements and reports the results in its Battery/Lead Status Report (see page 11-17).

Pacing Threshold Test 10-2

***Pacing Lead Impedance
Test 10-6***

***High Voltage Lead Impedance
Test 10-8***

Test Charge 10-12

Pacing Threshold Test

The Pacing Threshold Test enables you to determine the patient's atrial and ventricular pacing stimulation thresholds. The test consists of three parts:

- selecting test values for pacing amplitude, pulse width, pace blanking, and pacing rate;
- delivering pacing pulses that capture the heart;
- gradually decreasing the pulse width, automatically or manually, until pacing capture is lost.

For the automatic option (**Auto Decrement = ON**), the AMD delivers groups of non-adaptive pacing pulses as you press and hold , decreasing the pulse width for each group of pulses. For the manual option (**Auto Decrement = OFF**), you must decrease the pulse width manually by selecting ☒.

◆ **Operating Considerations**

Aborting the Test – As a safety precaution, the programmer displays an **ABORT** button on the Pacing Threshold Test screen.

Inhibiting Pacing – At any time during a threshold test, you can inhibit the pacing output of the AMD in order to evaluate the patient's intrinsic rhythm. If more than 1.76 seconds pass with the pacing output inhibited and no sensed ventricular events, the AMD aborts the inhibit function and reverts to operation according to the present parameter values. To inhibit the pacing output:


1. From the Pacing Threshold Test screen, select **INHIBIT**.
2. Select **DELIVER**. A message indicates that the command is causing inhibition.
3. To obtain a recording of the patient's natural rhythm, press the desired paper speed key on the printer/recorder. The ECG trace should not show any pacing stimuli.

◆ **How To Perform a Pacing Threshold Test**

1. From the **TESTS** menu, select **PACING THRESHOLD**. The programmer displays the Pacing Threshold Test screen (partial screen shown below).
2. Select appropriate **Chamber**.
3. Select starting Test values, or accept the values displayed.
 - a. To change the starting Pulse Width value, increase or decrease the value by pressing **^** or **v**.
 - b. To change the Lower Rate, Amplitude, or PAV (atrium only) values, select the parameter value and select the new starting value.
4. Position the programming head over the AMD. Hold it steady for the remainder of the procedure.

Pacing Threshold Test
Programmable Parameters
(circled)

DATA		TESTS		PARAMETERS		END SESSION		SPECIAL		PRINT	
PACING THRESHOLD: Press and hold DELIVER to pace.											
		PERMANENT		TEST						INHIBIT	
Pacing Mode:		VVI		VVI							
Lower Rate(ppm):		60		60				Chamber:		VENTRICLE	
Amplitude(V):		5		4							
Pulse Width(ms):		0.5		0.5				^		v	
								AUTO DECREMENT:		ON	

5. Press and hold **DELIVER**.
 - a. With **AUTO DECREMENT: ON**, the programmer decreases the pulse width automatically every six pulses. An audible beep confirms each decrement. The current value is displayed in the **TEST** column.
 - b. With **AUTO DECREMENT: OFF**, you can decrease the pulse width manually using the  button, then press **DELIVER** to deliver the pacing pulses.
6. Observe the ECG for loss of capture. When capture is lost, immediately release **DELIVER** to stop the test and restore the AMD to its pre-test state. The final test values remain displayed.

Pacing Lead Impedance Test

The Pacing Lead Impedance Test delivers a single pacing pulse to each chamber (AAT/VVT) at a fixed tilt and amplitude. After the next paced or sensed event, the programmer calculates and displays the lead impedance with a time stamp.

When a Pacing Lead Impedance Test is performed, a battery voltage measurement is also made (see "Battery/Lead Status" on page 11-17).

◆ **How To Perform a Pacing Lead Impedance Test**

1. Interrogate the AMD if you have not already done so.
2. From the **TESTS** menu, select **PACING LEAD IMPEDANCE**. The programmer displays the Pacing Lead Impedance Test screen (partial screen shown below).
3. Position the programming head over the AMD. Hold it steady for the rest of the procedure.
4. Select **DELIVER**. Wait for programming confirmation and a test in-progress message. After confirmation, observe one of the following:
 - If successful, the programmer updates the impedance values on the screen.
 - If unsuccessful, the programmer displays a message that briefly describes why the test could not be performed and emits a "not confirmed" tone.

Pacing Lead Impedance
Test Programmer Screen

DATA	TESTS	PARAMETERS	END SESSION	SPECIAL	PRINT
Interrogation complete.					
MOST RECENT APACE LEAD IMPEDANCE:			MOST RECENT UPACE LEAD IMPEDANCE:		
Oct 18, 1996 11:18:17			Oct 18, 1996 11:18:17		
Impedance(ohms): 888			Impedance(ohms): 786		

High Voltage Lead Impedance Test

In the High Voltage Lead Impedance Test, the AMD delivers a 0.2 joule monophasic pulse across the high voltage pathway you select, calculates the pathway impedance, and displays the result.

The high voltage pathway impedance is also measured automatically with every defibrillation or cardioversion pulse (see “Battery/Lead Status” on page 11-17).

You can choose synchronous or asynchronous delivery for the 0.2 joule pulse.

- For synchronous pulse delivery, the pulse is delivered at the first sensed R-wave. (You can also select a delay interval after the R-wave.)
- For an asynchronous pulse delivery, the AMD delivers three pacing pulses at the programmed bradycardia pacing settings, then delivers the 0.2 joule pulse.

◆ **Operating Considerations**

Aborting the Test – Throughout the test, you may select the button from any message window to stop the test.

Capacitor Formation in Progress – If a capacitor formation is in progress when you initiate the test, the programmer allows you to cancel or proceed with the test. If you choose to proceed, the capacitor formation is invalidated.

Failure to Synchronize – If the AMD cannot synchronize to a sensed event, or if a paced event occurs immediately after the start of the test, the shock aborts and the window below is displayed. Select or to restart the test.

Unable to synchronize test shock. Charge not delivered.
Select RETRY or DELIVER to restart test.

System Tests

High Voltage Lead Impedance Test

◆ How To Perform a HV Lead Impedance Test



Warning: Keep an external defibrillator immediately available and on standby.

1. From the **TESTS** menu, select **H.V. LEAD IMPEDANCE**. The programmer displays the High Voltage Lead Impedance Test screen (partial screen shown below).
2. Select the high voltage **Pathway** you wish to test.
3. Select either synchronous or asynchronous pulse delivery:
 - For a synchronous pulse delivery, toggle the value for the **Sync Required:** field to **YES** and select a **Pulse Delay(ms)** value.
 - For an asynchronous pulse delivery, toggle the value for the **Sync Required:** field to **NO**.

H.V. Lead Impedance Test
Programmable Parameters
(circled)

DATA	TESTS	PARAMETERS	END SESSION	SPECIAL	PRINT
HIGH VOLTAGE LEAD IMPEDANCE: Select options. Select DELIVER to start test.					
MOST RECENT H.V. LEAD TEST (0.2J MONOPHASIC):			Pathway: CATH BUC		
No previous test data.			Pulse Delay(ms) 8		
Impedance(ohms):			Sync Required: YES		
CAUTION: VF may be induced. Backup external defibrillator should be present.					

4. Select **CONTINUE** from the message window. Position the programming head over the AMD, and hold it steady for the remainder of the procedure.
5. Select **DELIVER**. The programmer emits a "successful programming" tone and displays the window shown below.

High Voltage lead impedance test in progress.

CANCEL

Test Charge



Warning: If the charge time exceeds 30 seconds, replace the AMD to protect against potential loss of AMD function (see “End of Life (EOL) Indicators” on page 13-4).

The Test Charge feature allows you to manually charge the AMD’s capacitors to their full energy, or to dump any charge remaining on the capacitors. After a Test Charge, the charge remains on the capacitors until either it dissipates (about 10 minutes), you initiate a manual therapy or dump procedure, or an automatic high voltage therapy is delivered.

Note: A charge must remain on the capacitors for at least ten minutes to register as an AMD capacitor formation.



How To Perform a Test Charge

1. Interrogate the AMD if you have not already done so.
2. From the **TESTS** menu, select **TEST CHARGE**. The programmer displays the Test Charge screen (partial screen shown on following page).
3. Confirm that the **OPERATION TO PERFORM:** value field displays **CHARGE**. If it displays **DUMP**, select the value field. The value changes to **CHARGE**.
4. Position the programming head over the AMD. Hold it steady for the rest of the procedure.

5. Select **DELIVER**. The programmer opens a test in-progress window and initiates a test charge to full energy.
 - Following a successful charge, select **CONTINUE** or **INTERROGATE** to update the display with values from the test charge.
 - If the test charge was not successful, the programmer displays an explanatory message and emits a "not confirmed" tone.

Test Charge
 Programmable Parameter
 (circled)

DATA	TESTS	PARAMETERS	END SESSION	SPECIAL	PRINT
TEST CHARGE: Select DELIVER to charge capacitors to 27J.					
OPERATION TO PERFORM: CHARGE					
MOST RECENT CHARGE TO FULL ENERGY:			LAST CAPACITOR FORMATION:		
Oct 09, 1995 12:05:22			Oct 06, 1995 11:43:27		
Energy(J): 0.4 - 26.8			Time stamp updated when 27J		
Charge Time(sec): 5.23			charge held for 10 minutes.		

◆ **How To Dump the Capacitor Charge**

1. From the Test Charge screen, toggle the **OPERATION TO PERFORM:** value field to **DUMP**. If it displays **CHARGE**, select the value field. The value changes to **DUMP**.
2. Position the programming head and select **DELIVER**. The AMD dumps any charge on its capacitors, which can take up to twenty seconds.

System Tests
Test Charge

Monitoring Features

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Monitoring Overview

The AMD monitors both the patient and the implanted system, and stores the following types of data in memory (Figure 11-1). During a patient session, you can view the data on the screen or print it (page 12-16) in report form.

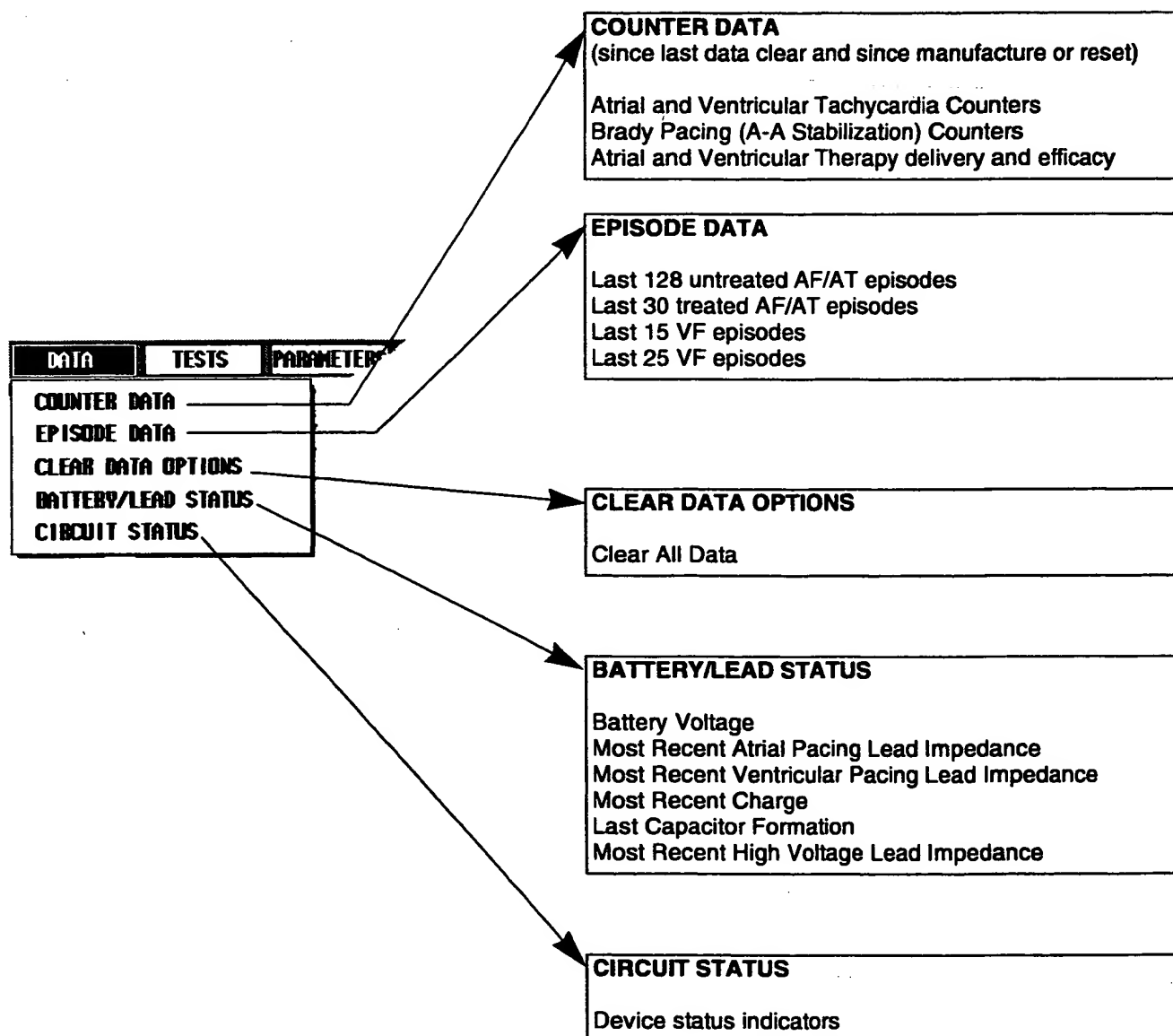


Figure 11-1. AMD Data Overview

Counter Data

The AMD continuously stores significant events such as detected tachyarrhythmia episodes and therapy deliveries as Counter Data in memory. There are four Counter Data screens:

- Detection
- VF Therapy
- VT Therapy
- AF/AT Therapy

The programmer allows you to view the data on the screen or print the data as a Counter Data Report (page 11-5) or as part of a Full Report. Figure 11-2 shows an AF/AT Therapy Counter Data screen.

DATA	TESTS	PARAMETERS	END SESSION	SPECIAL	PRINT	
COUNTER DATA:						
DETECTION	VF THERAPY	VT THERAPY	AF/AT THERAPY			
Date Interrogated: Oct 18, 1996 15:36:07						
Counters Last Cleared: Oct 18, 1996 00:27:57						
AF THERAPY	Rx1	Rx2	Rx3	Rx4	Rx5	Rx6
INITIATED:	5	1	0	0	0	0
SUCCESSFUL:	0	1	0	0	0	0
ABORTED:	0	0	0	0	0	0
INEFFECTIVE:	4	0	0	0	0	0
UNDETERMINED:	1	0	0	0	0	0
AT THERAPY						
INITIATED:	0	0	0	1	0	0
SUCCESSFUL:	0	0	0	0	0	0
ABORTED:	0	0	0	1	0	0
INEFFECTIVE:	0	0	0	0	0	0
UNDETERMINED:	0	0	0	0	0	0

Figure 11-2. AF/AT Therapy Counter Data Screen

◆ **How To Display Counter Data**

1. Interrogate the AMD if you have not already done so.
2. From the **DATA** menu, select **COUNTER DATA**.
3. Select one of the following:

DETECTION **VF THERAPY** **VT THERAPY** **AF/AT THERAPY**

4. To print the counter data displayed on the programmer screen, select **CURRENT SCREEN** from the **PRINT** menu. See also page 12-18 for information on printing counter data as part of a Custom or Full Summary Report.

◆ **How To Clear Counter Data**

Note: You may wish to print the episode data before clearing it. The episode records are permanently erased when you clear the episode data.

1. From the **DATA** menu, select **CLEAR DATA OPTIONS**.
2. Select **CLEAR ALL DATA** to clear all detection and therapy counters. **Note:** All stored episode data are also cleared.
3. Select **CONTINUE** or **PROGRAM**.

◆ **Operating Considerations**

A **CLEAR IN PROGRESS** message appears if you have not interrogated the AMD since the last clearing.

Counter Data Report

Table 11-1 summarizes the information in a Counter Data Report.

Table 11-1. Counter Data Report

Category	Counter Value
Time of last interrogation	
Time when counters were last cleared	
Detection Counters*	
Treated AF/AT Episodes	0, 1, ..., 255, ≥ 255
Untreated AF/AT Episodes	0, 1, ... ≥ 65535
VF Episodes	0, 1, ..., 255, ≥ 255
VT Episodes	0, 1, ..., 255, ≥ 255
Atrial Rate Stabilizations Runs (1 or more beats)	0, 1, ... ≥ 16777215
Therapy Counters* (per programmed therapy)	
Initiated	0, 1, ..., 255, ≥ 255
Successful	0, 1, ..., 255, ≥ 255
Aborted	0, 1, ..., 255, ≥ 255
Ineffective	0, 1, ..., 255, ≥ 255
Converted†	0, 1, ..., 255, ≥ 255
Efficacy undetermined	0, 1, ..., 255, ≥ 255

* If a Detection counter or any of its Therapy counters reaches its maximum value, all those counters stop incrementing until they are cleared.

† Redetection of a different ventricular arrhythmia (VF converted to VT, or vice versa). **Note:** "Converted" does not appear as an atrial therapy outcome.

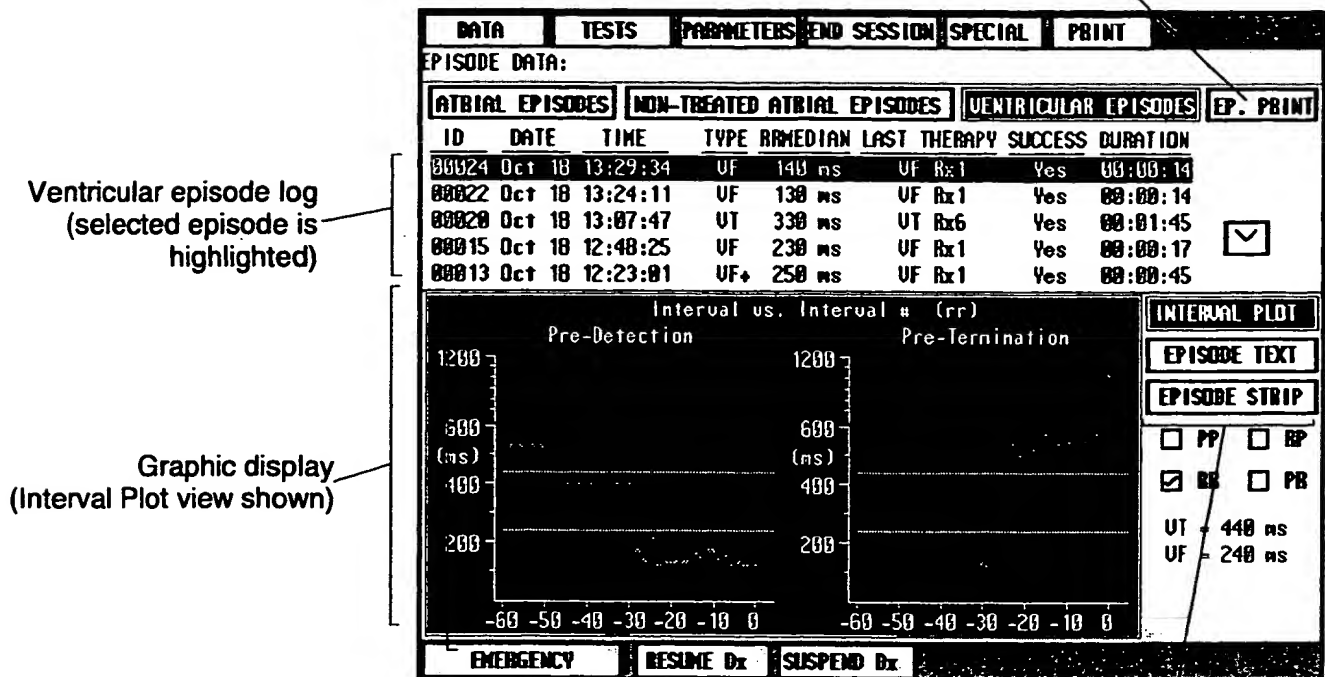
Episode Data

The AMD stores episode data for each detected atrial or ventricular tachyarrhythmia episode, and for non-treated atrial episodes. An episode log lists summary information on the recent episodes (see Figure 11-3).

Each stored atrial and ventricular episode provides the following patient management tools:

- Interval Plots showing P:P, R:R, R:P and/or P:R intervals (page 11-10)
 - 60 pre-therapy and 60 pre-termination intervals for atrial episodes
 - 60 pre-detection and 60 pre-termination intervals for ventricular episodes
- An Episode Text report (page 11-11)
- Stored EGM with Marker Channel™ and supplemental annotations (page 11-12)

Select to print Episode Data Report (page 11-16)
for the selected episode.



Select appropriate button to toggle graphic display between
Interval Plot, Episode Text, and Episode Strip views
of the selected episode.

Figure 11-3. Ventricular Episode Data Screen Example

◆ **How to Display Episode Data**

1. Interrogate the AMD if you have not already done so. Select "YES" in the pop-up box to include Episode Data in the interrogation (see below).

Select CONTINUE or INTERROGATE to interrogate items below:
Parameters, Counters, and Battery/Lead Status plus
☒ YES ☐ NO Episode Data

2. From the **DATA** menu, select EPISODE DATA.
3. Select one of the following options:

ATRIAL EPISODES
NON-TREATED ATRIAL EPISODES
VENTRICULAR EPISODES

The stored episodes appear in reverse chronological order (the most recent episode appears first on the list).

4. Select a treated atrial or ventricular episode from the list to view its Interval Plot, Episode Text, or Episode Strip (see page 11-10 through page 11-12).
5. To print episode data displayed on the programmer screen, select **CURRENT SCREEN** from the **PRINT** menu. See also page 12-18 for information on printing episode data as part of a Custom or Full Summary Report.

◆ **How To Clear Episode Data**

Note: You may wish to print the episode data before clearing it. The episode records are permanently erased when you clear the episode data.

1. From the menu, select the **CLEAR DATA OPTIONS** menu option.
2. Select to clear all stored episode data, including stored EGMs, interval records, and date/time records. **Note:** All counter data are also cleared.
3. Select or .

◆ **Operating Considerations**

Use the "scroll" buttons to display additional stored episodes.

An **Episode In Progress** message for the first episode in the list means that the episode was in progress at the time of interrogation. If you interrogate while an episode is in progress, the programmer only retrieves a portion of that episode's data.

An **??? INVALID DATA RECEIVED** message in the summary list indicates that the programmer could not interpret the data it retrieved from the AMD.

A **No EPISODE DATA stored in the AMD** message in the summary list indicates that no Episode Data was retrieved from the AMD during the last interrogation.

Interval Plot View

When you first select an episode¹ from the summary list, the lower half of the screen displays two Interval Plots:

- Atrial episodes: 60 intervals prior to therapy and 60 intervals prior to episode termination
- Ventricular episodes: 60 intervals prior to detection and 60 intervals prior to episode termination

The interval plots represent each sensed interval (P:P, R:R, R:P, and/or P:R) along the X-axis, with its interval value in milliseconds along the Y-axis (Figure 11-4).

◆ Operating Considerations

The Y-axis includes intervals from 120 to 1200 milliseconds, with graduations at 100 milliseconds.

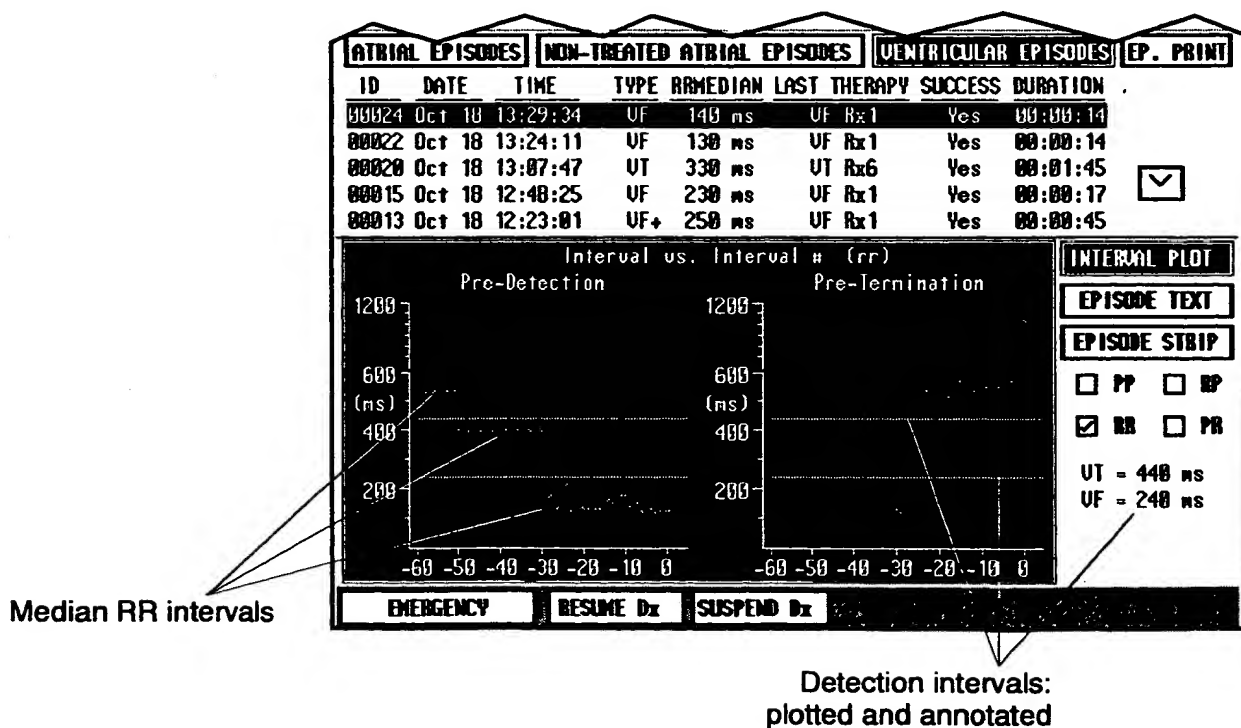


Figure 11-4. Interval Plot Example (Ventricular Episode)

1. Interval plots are not stored for non-treated atrial episodes.

Episode Text View

When you select the **Episode Text** view,¹ the screen shows a text description of the selected episode, including the summary, programmed detection configuration and therapy sequence for the episode.

◆ Operating Considerations

To view all the episode text, use the "scroll" buttons in the lower right portion of the screen.

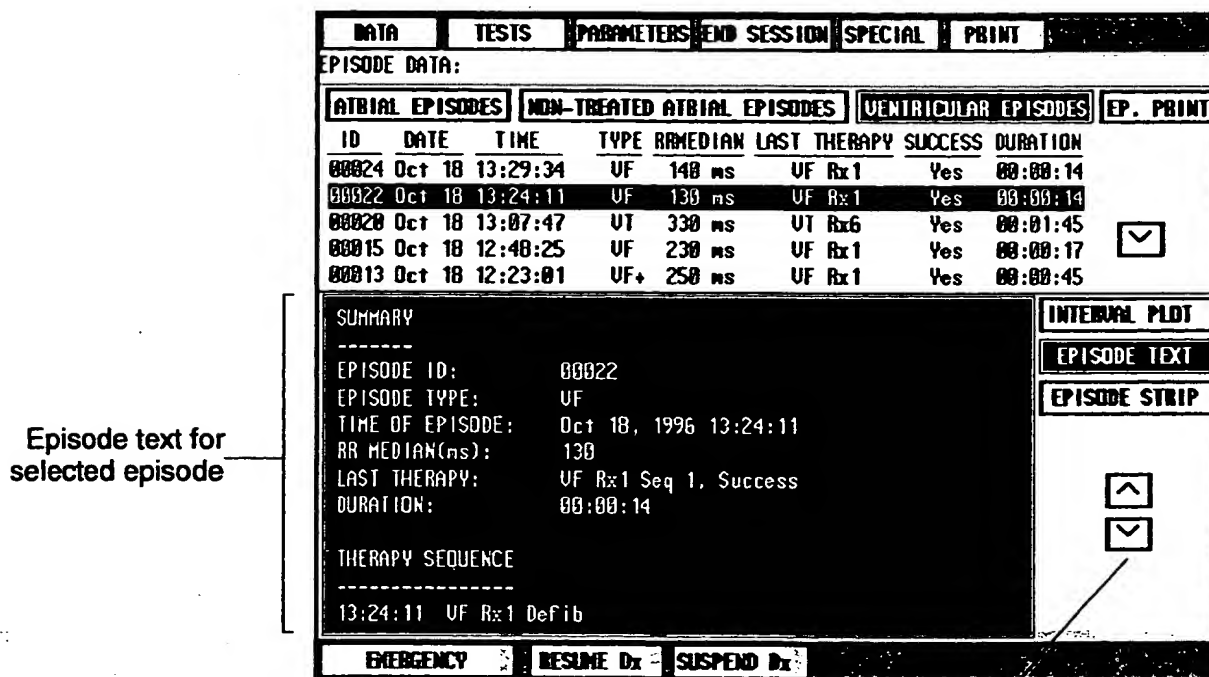


Figure 11-5. Episode Text Display Example (Ventricular Episode)

1. Episode Text is not stored for non-treated atrial episodes.

Episode Strip View

When you select the **Episode Strip** button, the screen displays the stored electrogram (see page 11-13) and Marker Channel™ (see page 11-24 for a key to the Marker Channel symbols). For each treated tachyarrhythmia episode, the AMD stores intracardiac electrogram and Marker Channel data, as follows:

Episode Type	Stored EGM	Marker Channel Data
Atrial	5 seconds pre-therapy	60 events pre-therapy; 60 events pre-termination
Ventricular	5 seconds pre-detection	60 events pre-detection; 60 events pre-termination

◆ Operating Considerations

Because of the density of the EGM data, there may be a delay in displaying the Episode Strip view. The message **Please wait . . .** may appear, along with an option to cancel the EGM strip display.

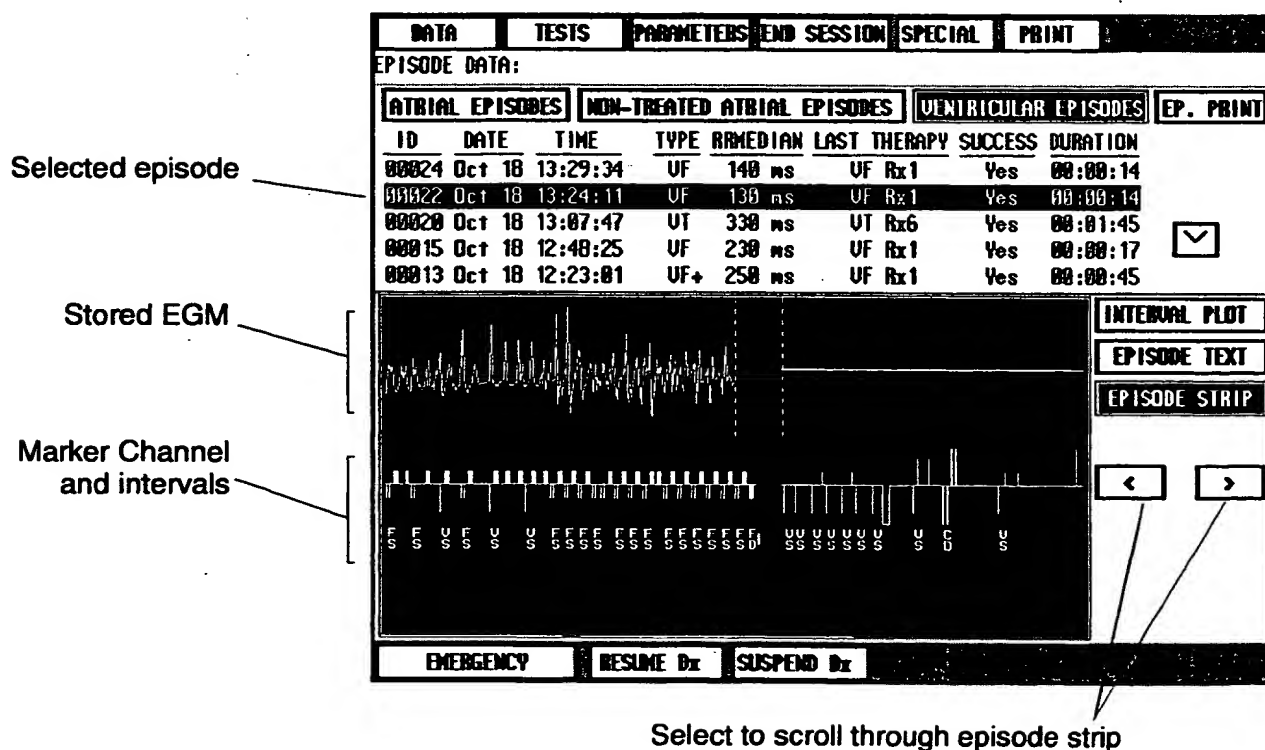


Figure 11-6. EGM Strip Display Example (Ventricular Episode)

EGM Storage

The AMD stores up to 5 seconds of electrogram for each treated tachyarrhythmia episode (pre-therapy for atrial episodes; pre-detection for ventricular episodes), as sensed on the electrodes programmed as the Channel 1 EGM Source. The stored electrogram is annotated with Marker Channel™ and supplemental annotations (see “Real-Time Data” on page 11-22).

◆ **Programmable Parameters**

EGM Sources	Sensing sources for the Channel 1 (Stored and on-screen) and Channel 2 (on-screen) EGM traces.
Wideband Source	Further specifies the source of the “Wideband” EGM, if used, for Channel 1 EGM.
Wideband Range (mV)	Amplifier gain range for the Channel 1 “Wideband” EGM, if used.

◆ **Programming Considerations**

The AMD’s cardiac interval measurements are always derived from the bipolar A-Sense and V-Sense EGMs. Tachyarrhythmia detection, synchronization, and therapy are not affected by your selection of an EGM source.

You can display both the Channel 1 and Channel 2 EGMs on screen, and record them on paper in real-time.

Episode Summary Reports

Episode Summary Reports provide an overview of stored episodes. See page 12-18 for instructions on printing Episode Summary Reports.

Non-Treated Atrial Episode Summary Report

Table 11-2. Non-Treated Atrial Episode Summary Report

Category	Value
Episode Summary	
Episode ID Number	
Time/date of preliminary detection	
Rhythm type at preliminary detection	AF, AT
Atrial cycle length at preliminary detection	
Episode duration	
Number of Non-Treated Atrial Episodes Stored	Up to 128.

Atrial Episode Summary Report

Table 11-3. Atrial Episode Summary Report

Category	Value
Episode Summary	
Episode ID Number	
Time/date of preliminary detection	
Rhythm type at preliminary detection	AF, AT
Atrial cycle length at preliminary detection	
Episode duration	
Last therapy delivered and outcome	
VT/VF detected	
Number of Atrial Episodes Stored	Up to 30.

Ventricular Episode Summary Report

Table 11-4. Ventricular Episode Summary Report

Category	Value
Episode Summary	
Episode ID Number	
Time/date of detection	
Rhythm type at detection	VF, VT, VF+, VT+ ("VF+SVT" or "VT+SVT"), VF*, VT* (VT/VF Discrimination; see page 6-14).
Ventricular cycle length at detection	
Last therapy delivered and outcome	
Episode duration	
Number of Ventricular Episodes Stored	Up to 15 VF; up to 25 VT.

Episode Data Report

An atrial or ventricular Episode Data Report consists of an episode summary, therapy sequences, detection configuration, and EGM settings, followed by an EGM strip for the episode. See page 12-18 for instructions on printing Episode Data Reports.

Table 11-5. Episode Data Report

Episode Summary	
Episode ID Number	
Episode Type	AF, AT VF, VT, VF+, VT+ ("VF+SVT" or "VT+SVT"), VF*, VT* (VT/VF Discrimination; see page 6-14).
Time/date of detection	
Cycle length at detection	Median PP; median RR
Last therapy delivered and outcome	
Episode duration	
Therapy Sequence	
Time of therapy (ies)	
Type of therapy (ies)	Pacing: Therapies/sequences delivered. High Voltage: Charge time, energy, impedance, pathway, tilt.
Detection Settings	
Therapy Settings (atrial only)	
EGM Settings	Source, Range
Stored EGM	5 seconds prior to first atrial therapy; 5 seconds prior to VT/VF detection.
Pre-Therapy Intervals and Markers (atrial only)	60 events prior to first atrial therapy.
Pre-Detection Intervals and Markers (ventricular only)	60 events prior to VT/VF detection.
Pre-Termination Intervals and Markers	60 events prior to termination.

Battery/Lead Status

The AMD automatically and continuously monitors its battery and lead status throughout the life of the device. When you interrogate the AMD during a patient session, the programmer allows you to display and print the following data:

- Battery voltage
- Pacing lead impedances
- Charge times
- High voltage pathway impedances

See page 11-19 for more information on the battery and lead status measurements.

DATA	TESTS	PARAMETERS	END SESSION	SPECIAL	PRINT
BATTERY/LEAD STATUS:					
Date Interrogated: Oct 18, 1996 15:36:07					
BATTERY VOLTAGE:			MOST RECENT CHARGE:		
Oct 18, 1996 11:18:15			Oct 18, 1996 13:29:43		
Last Measured (V): 6.23			Energy(J): 0.1 - 27.3		
			Charge Time(sec): 6.13		
MOST RECENT ATRIAL PACE IMPEDANCE:			LAST CAPACITOR FORMATION:		
Oct 18, 1996 11:18:17			Oct 18, 1996 11:36:58		
Impedance(ohms): 808			Energy(J): 0.1 - 27.3		
			Charge Time(sec): 6.13		
MOST RECENT VENTRICULAR PACE IMPED:			MOST RECENT H.V. LEAD IMPEDANCE:		
Oct 18, 1996 11:18:17			Oct 18, 1996 13:29:43		
Impedance(ohms): 786			Pathway1: CAN>RUC		
			Pathway2: RUC>CAN		
			Delivered Energy (J): 24.8		
			Impedance(ohms): 38		
EMERGENCY	RESUME Dx	SUSPEND Dx			

Figure 11-7. Battery/Lead Status Screen Example

◆ ***How to View the Battery/Lead Status Data***

1. Interrogate the AMD if you have not already done so.
2. From the **DATA** menu, select **BATTERY/LEAD STATUS**. The programmer displays a screen like the one below.
3. To print the battery/lead information, select **CURRENT SCREEN** from the **PRINT** menu. See also page 12-18 for information on printing battery/lead status data as part of a Custom or Full Summary Report.

◆ ***Operating Considerations***

The values displayed may be either actual measurements or calculations based on actual measurements.

If the AMD has not measured a particular value since being reset, the date/time stamp area for that value will display the message **No measurement since reset.**

◆ ***How the Battery/Lead Measurements Work***

Battery Voltage – The AMD measures the battery voltage during a manual pacing lead impedance test. If the voltage fulfills either the Elective Replacement (ERI) or End of Life (EOL) indicator, the programmer sends a message recommending that you replace the device. Refer to “Longevity Expectations” on page 13-2 for more information on AMD longevity.

Pacing Lead Impedance Measurements – The AMD measures and stores the pacing lead impedances during a pacing lead impedance test.

High Voltage Lead Impedance Measurements – The AMD measures the high voltage pathway impedance after each delivered defibrillation or cardioversion therapy, and during a manual high voltage lead impedance test. A single path impedance is measured even when the pathway includes multiple cardioversion/defibrillation electrodes. “Pathway 1” and “Pathway 2” refer to the phases of a biphasic pulse. An open connection to one of the anodes may increase the path impedance slightly.

Device Status Indicators



The Device Status Indicators are important. Please inform your Medtronic representative if an indicator other than **MEMORY RETENTION OK**, **CHARGE CIRCUIT OK**, or **ATRIAL THERAPIES DISABLED** appears.

The AMD continuously monitors its own circuitry for memory retention capability, charging circuit status, and electrical (power-on) reset occurrence. With each interrogation, the programmer allows you to display and print the Device Status indicators.

Table 11-6. Device Status Indicator Messages

MEMORY RETENTION OK	No errors affecting AMD memory have been detected.
MEMORY ERROR OCCURRED	Memory retention error occurred. Please inform a Medtronic representative.
CHARGE CIRCUIT OK	No charge circuit errors have been detected.
CHARGE CIRCUIT TIMEOUT	One charging period has exceeded 30 seconds. The charge circuit is still active. Please inform a Medtronic representative.
CHARGE CIRCUIT INACTIVE	Three consecutive charging periods have each exceeded 30 seconds. The charge circuit is inactive. The AMD disables automatic therapy functions and manual operations except for Emergency VVI pacing. Please inform a Medtronic representative.
POWER-ON RESET OCCURRED	A power-on reset (POR) occurred. The AMD parameters are reset to nominal values, and the serial number is reset to the characters RESET . All AMD data is cleared. VF detection and VF therapies are enabled. Please inform a Medtronic representative.
POR AND MEMORY ERROR OCCURRED	Power-on reset and memory retention error occurred. AMD is reset as described above. Please inform a Medtronic representative.
ATRIAL THERAPIES DISABLED	All atrial therapies are disabled if VT or VF is detected immediately following an AF/AT therapy (i.e., before either AF/AT redetection or AF/AT episode termination is detected). Disabled atrial therapies must be re-enabled through the programmer.

◆ **How To View the Device Status Indicators**

- From the **DATA** menu, select **CIRCUIT STATUS**. To print the device status messages, select **CURRENT SCREEN** from the **PRINT** menu (see also page 12-18).

◆ **How to Clear the Device Status Indicators**

1. If the Circuit Status screen is not already displayed, select **DATA**.
2. Select **CIRCUIT STATUS**. Active device status indicators are displayed. If any indicator other than **MEMORY RETENTION OK** or **CHARGE CIRCUIT OK** is displayed, the programmer also provides a **CLEAR STATUS** button.
3. Select **CLEAR STATUS**.
4. If the programmer displays **MEMORY RETENTION ???** or **CHARGE CIRCUIT ???**, reposition the programming head and reselect **CLEAR STATUS** to clear the indicators.

◆ **Operating Considerations**

Under normal conditions, the screen displays only the two "OK" indicators:

MEMORY RETENTION OK
CHARGE CIRCUIT OK

If the AMD detected an error or unexpected device status, the programmer also displays the appropriate indicator in a dialog window with each programming or interrogation attempt until you clear the message manually.

You can make paper recordings of the EGM and Marker Channel waveforms as described in “Recording Real-Time Waveforms” on page 12-14.



Waveforms

Real-time data screens include either one or two high resolution waveform displays. Using on-screen buttons, you can select the waveform displayed. For each waveform displayed, on-screen buttons appear to the left of the waveform. The upper button to the left of each trace shows the waveform displayed.

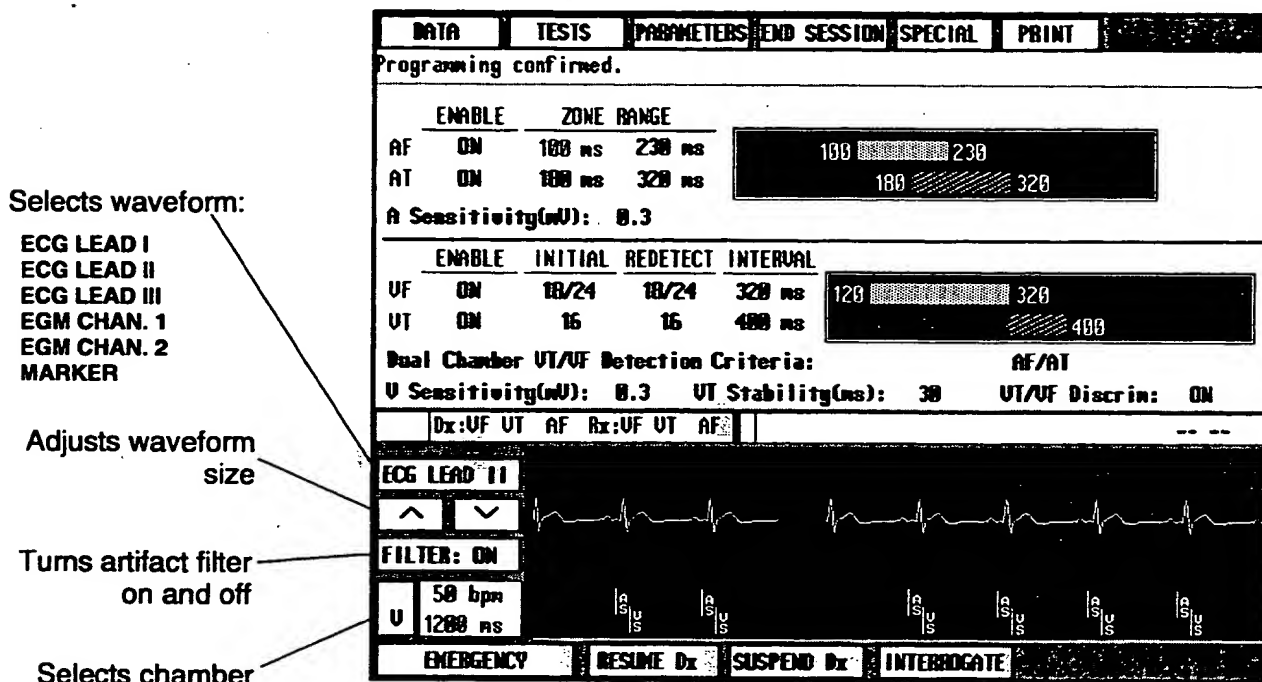


Figure 11-9. Real-Time Waveform Display

Holter Telemetry

When the Holter Telemetry feature is enabled, the AMD transmits EGM and Marker Channel data continuously for a programmable number of hours, regardless of whether the programming head is positioned over the device. Holter monitoring increases current drain on the AMD's battery, decreasing its longevity.

Marker Channel™ Symbols and Annotations

Real-time data screens include Marker Channel symbols and annotations (Figure 11-10). The annotations appear between the waveform displays on two-waveform screens and below the waveform display on one-waveform screens. They can also be displayed as a real-time waveform and recorded or printed via the programmer. See also "Supplemental Annotations" on page 11-26.

There is a hierarchy for the display of **atrial** markers:

1. If an atrial episode is in progress, AF Detection and AT Detection markers take precedence over all other atrial markers (except Atrial Pace). AF Detection and AT Detection markers appear **only** if an atrial episode is in progress, and **only** if the rhythm is classified as AF or AT.
Note: These markers do not necessarily represent beat-to-beat atrial cycle length information.
2. Atrial Sense, Atrial Refractory Sense, AT Sense, AT Sense via AF, and AF Sense markers are displayed **only** if the atrial rhythm is unclassified (i.e., if AF Detection and AT Detection markers are not displayed).
Note: These markers represent beat-to-beat atrial cycle length information.

For example, consider a hypothetical, ongoing atrial episode during which an atrial rhythm classified as AF becomes temporarily unclassified (see note on page 5-5), and the atrial cycle length is in the AF detection zone. In such a case, AF Detection markers would cease to be displayed, and AF Sense markers would be displayed. If the atrial rhythm were then to become classified as AF again, the AF Sense markers would cease to be displayed, and AF Detection markers would again be displayed.

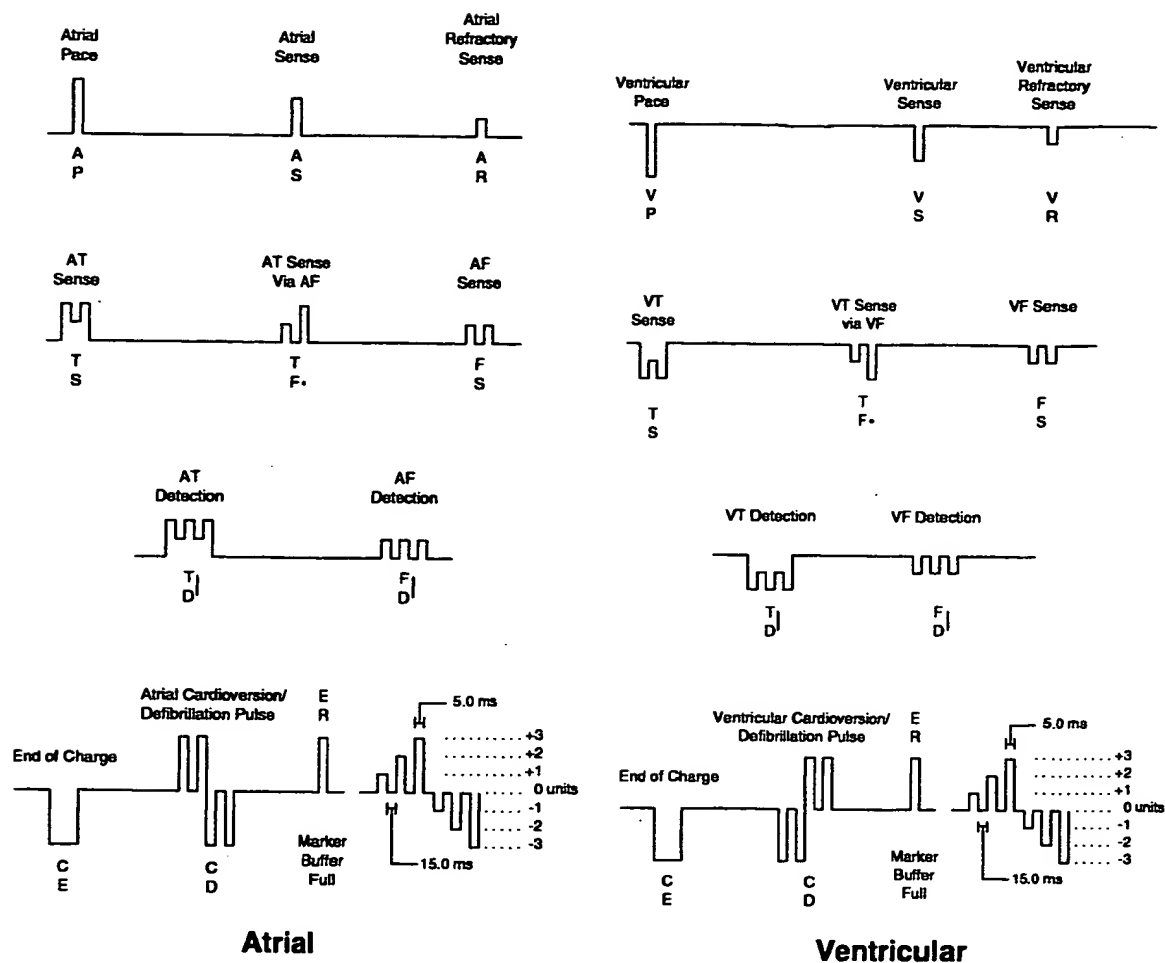


Figure 11-10. Marker Channel™ Symbols and Annotations

Supplemental Annotations

Additional annotations describing the type of episode in progress, the type of detection, and Mode Switch operation are displayed at the top of the strip chart recording (see also "Detection Status" on page 11-28). **Note:** Supplemental annotations are printed on the strip chart only if you are on a programmer screen that is displaying the Device Status Line (page 11-27).

Table 11-7. Supplemental Annotations

*	No episode in progress
*A	Atrial tachyarrhythmia episode in progress
*V	Ventricular tachyarrhythmia episode in progress
AF	Rhythm classification: Atrial fibrillation
AT	Rhythm classification: Atrial tachycardia/flutter
VF19	Single chamber VF detection
VT19	Single chamber VT detection
VF+	VF + SVT dual tachycardia detection
VT+	VT + SVT dual tachycardia detection
V_AF	Dual Chamber VT/VF Detection: AF/AT Criterion (A. Fib)
V_AT	Dual Chamber VT/VF Detection: AF/AT Criterion (A. Tach/FI)
AVNT	Dual Chamber VT/VF Detection: Other 1:1 SVTs Criterion
ST	Dual Chamber VT/VF Detection: Sinus Tach Criterion
NSR	Normal sinus rhythm via ST Criterion
VF*	VF detection via VT/VF Discrimination
VT*	VT detection via VT/VF Discrimination
MS 00	Mode Switch is DDD
MS Delta	Mode Switch to DDI _{delta}
MS Dwell	DDI _{dwell} Switchback Delay
MS Fall	Mode Switch to DDI _{fall}
MS ??	Mode Switch back to DDD

Device Status Line

The Device Status Line (Figure 11-11) displays:

- Automatic detection status
- Programmed detection and therapy configuration
- Episode in progress indicator
- Episode and therapy status

Note: If the pacing rate is faster than 600 ppm (100 ms intervals), the AMD cannot send this data to the programmer.

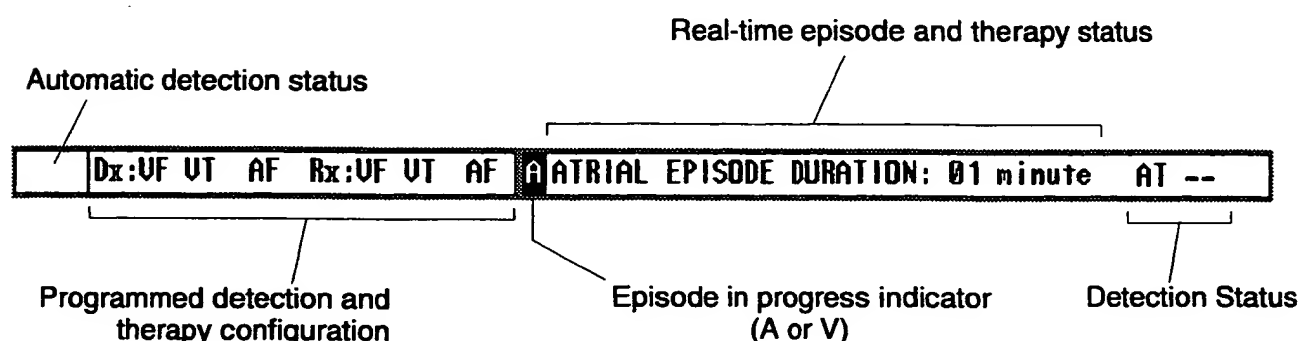


Figure 11-11. Device Status Line

Automatic Detection Status – The programmer displays **SUSP** if detection is suspended (magnet mode). The field is blank if detection has resumed (magnet cancelled). If the state is unknown as a result of a loss of telemetry, the programmer displays question marks (????).

Programmed Detection and Therapy Configuration – This section shows detection (Dx:) zones and therapy (Rx:) zones that are enabled. It indicates detection zones and therapies not enabled with dashes (–). AF is listed for both AF and AT detection and for AF and/or AT therapy.

Episode in Progress Indicator – Displays **A** or **V** when a tachyarrhythmia episode is in progress. The programmer clears the symbol when the AMD determines that the episode has terminated. If a dual tachycardia is in progress, only a **V** will be displayed.

Real-Time Episode and Therapy Status – This section displays messages that inform you of:

- AF and AT episode duration
- VT and VF event counts
- Therapy in progress: **VT THERAPY 1/2 IN PROGRESS** indicates that sequence two of VT therapy one is in progress
- Manual operation in progress
- Charging in progress

If telemetry is lost (due to noise during charging, for example) the message **NOT RECEIVING MARKER SUPPLEMENT** is displayed.

Detection Status – This section displays the type of detection occurring. See also “Supplemental Annotations” on page 11-26.

AF = atrial fibrillation rhythm classification
AT = atrial tachycardia rhythm classification
VF19 = ventricular fibrillation detection
VT19 = ventricular tachycardia detection
VF+ = dual chamber VF + SVT tachycardia detection
VT+ = dual chamber VT + SVT tachycardia detection
VF* = VF detection via VT/VF Discrimination feature
VT* = VT detection via VT/VF Discrimination feature

Programmer and Software

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Programmer/Software Overview

The programmer and AMD application software provide you with important patient management capabilities:

- Interrogate and program the AMD's parameter values.
 - Display and record real-time monitoring information from the device:
 - Lead I, II, and III ECG waveforms
 - Atrial, ventricular, and 'wideband' EGM waveforms
 - Annotated Marker Channel™ waveforms
 - Heart rate and interval measurements
 - Key AMD status messages
 - Retrieve AMD stored events and episode data.
 - Print AMD reports.
 - Conduct system tests and EP studies:
 - Pacing threshold tests
 - Pacing and high voltage lead impedance tests
 - Capacitor test charges
 - Electrophysiologic (EP) study inductions and therapies
- Note:** Tachyarrhythmia software applications do not support the Artifact Setup and Set Site Nominals features.
- Save AMD to a disk and read AMD data from a disk.

General Precautions

Loss of Power

If power to the programmer is unexpectedly lost during a patient session, the AMD completes the last programmed operation and remains as programmed. If this occurs, first lift the programming head away from the AMD to make sure that automatic detection resumes, then turn the programmer on again. Normal programmer operation should resume.

Programming Head Position

If the programming head is not aligned correctly over the AMD, you may not be able to establish a telemetry link between the AMD and programmer. The programmer indicates a loss of telemetry by turning off the green lights and turning on the amber light in the programming head light array.

Unresponsive Screen

If the screen becomes unresponsive or if you cannot establish telemetry between the AMD and programmer after repeated attempts, turn the programmer off, then on again. Normal programmer operation should resume. Please inform your Medtronic representative of this occurrence.

Note: After turning the programmer off, always wait at least five seconds before turning it back on.

Loss of Telemetry During Charging

The telemetry link between the programmer and AMD may be lost during high voltage capacitor charging periods. You should not have to realign the position or the programming head. Upon completion of the charging period, proper telemetry between the programmer and AMD should resume.

Electromagnetic Interference (EMI)

Exposure to EMI may briefly interrupt programming and/or telemetry operations. Keep the programmer and AMD away from EMI sources during a programming session. EMI sources include, but are not limited to, the following:

- Nuclear Magnetic Resonance Imaging (MRI) equipment
- Therapeutic Diathermy
- Defibrillation equipment
- Electrocautery
- Lithotripsy
- High voltage systems
- Radio transmitters
- Theft prevention equipment
- Current-carrying conductors
- High-powered electromagnetic fields

Ending a Patient Session

Always end a patient session properly before starting a programming session with another patient:

1. Select **END SESSION**.
2. The programmer displays a message asking you to confirm your selection. Select **YES** to confirm.

Setting Up the Programmer

Before setting up the programmer, select a sturdy location without blocking the vents on the front, right, and left. The programmer uses AC power, so the location must be near an outlet.

For complete information on setting up and using the programmer, refer to the *9790c Programmer Description and Setup* manual provided with your programmer.

1. **Position the display.** Press inward on the two buttons located under the triangles and lift the display up. Place it at a comfortable viewing angle.
2. **Connect the ECG cable.** Press the compartment latch and lift open the front compartment. Line up the red dots on the ECG cable and ECG input located inside the front storage compartment, and plug the cable into the connector.
3. **Connect the programming head.** Plug the programming head cable into the programming head input located inside the front storage compartment. It fits only one way with the connector screw heads facing down.
4. **Close the front compartment.** With the touch pen, ECG cable, and programming head out of the storage compartment, close the front compartment. The shoulder strap can be stored in either the front or rear compartment.
5. **Store the touch pen.** Put the touch pen in the holder located in the right corner of the display.
6. **Connect the power cord.** The programmer automatically adjusts to the available line power. Insert the female plug on the power cord into the power cord receptacle. Connect the other end of the cord to an AC power outlet.
7. **Turn the Programmer On.** Press inward on the top of the ON/OFF switch located on the left side. Before operating the programmer for the first time, you must install the software. (Instructions are included with the software disks.)

Connecting External Devices

An analog output port on the right side of the programmer provides a connection for an external recorder or monitor. A special adaptor is required for the connection of an external device to the analog output port. (This adaptor is not included with the programmer; contact your Medtronic representative for more information.)

The adaptor has four BNC-style connectors:

- A Surface ECG
- B EGM Channel 2
- C EGM Channel 1
- D Marker Channel™

A switch on the adaptor allows you to select an output level of either ± 1 volt or ± 5 millivolts.

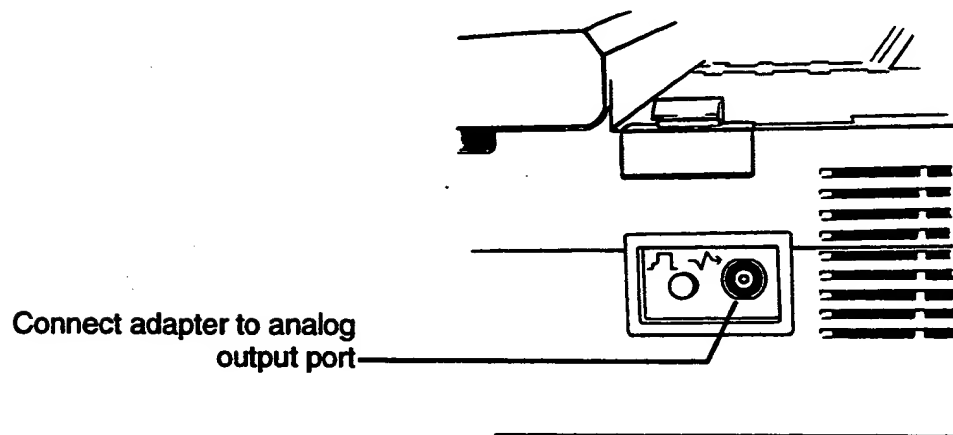


Figure 12-1. Connecting External Devices

Calibrating an External Recording

On an externally connected recorder or monitor, the Marker Channel™ trace does not include marker annotations. You will need to identify the marker symbols based on their relative amplitudes. Selecting the **EXTERNAL CAL PULSE** option from the **SPECIAL** menu adds the reference diagram (Figure 12-2) to the trace as an aid to identifying the markers.

The reference diagram appears on the programmer (real-time waveform display and recording) and on the externally connected monitor or recorder.

Note: You can press the calibrate button located next to the analog output port on the right side of the programmer as an alternative to using the **EXTERNAL CAL PULSE** option.

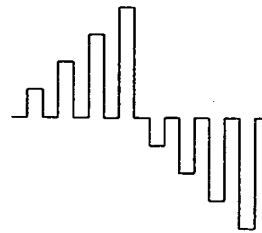


Figure 12-2. Marker Calibration Diagram

Calibrating the EGM Signal – You can also use the **EXTERNAL CAL PULSE** option to obtain an amplitude reference diagram for the EGM channel (Figure 12-3).

The amplitude reference diagram applies to both ECG and EGM traces, and is displayed and recorded by the programmer and the externally connected monitor or recorder.

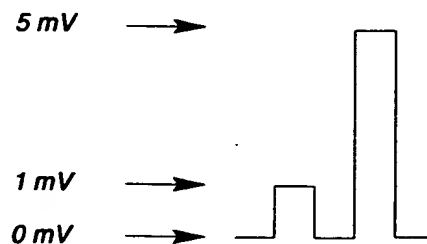


Figure 12-3. EGM Calibration Diagram

Positioning the Programming Head

For an implanted AMD, hold the programming head directly against the patient's skin, but without undue pressure. The best position is that which lights the greatest number of green lights on the programmer head.

Verifying Proper Telemetry

Any successful interrogation or programming verifies proper communication between the AMD and programmer.

If the telemetry link is unsuccessful even when the green lights are lit, reposition the programming head by one or two centimeters and watch the Device Status Line until **SUSP** is displayed. This indicates that the AMD is in Suspended Detection mode, responding to the magnet in the programming head. The AMD and programmer should now communicate.

Setting the Programmer Clock

The programmer uses an internal clock for certain programming functions requiring a date and time stamp (such as for printing the date and time at the bottom of a report).

◆ **How to Set the Programmer Clock**

1. From the Model Selection Screen, select **SETUP...**.
2. Select **SET TIME AND DATE**.
3. Using the **▲** and **▼** buttons, select Month, Day, Year, Hours, and Minutes values.
4. Select **ACCEPT** or **RETURN**.

Displayed or printed time stamps for data stored in the AMD are calculated from a counter in the device and the programmer clock. For this reason, resetting the programmer time and date may have corresponding effects in the time stamps interrogated from the AMD. This may also cause the displayed or printed time stamps to change slightly as a result of being interrogated by different programmers.

Using the 9790 Programmer

Visual Conventions

SHOW PRESENT

The programmer displays a **SHOW PRESENT** button when a pending value exists for at least one parameter on the current screen. When you press or press and hold this button, the programmer displays the present values for the parameters currently on the screen.

PROGRAM

Selecting the on-screen **PROGRAM** button sends all pending parameter values for the current screen to the AMD.

Present and Nominal Indicators

The present indicator ► appears in a value selection window just to the left of the value in the list that is the current permanently programmed value. The nominal indicator ▷ appears just to the left of the value in the list that is the Medtronic Nominal value. If the present value and Medtronic Nominal values are the same, the present indicator takes precedence.

Pending Values

When you select a value to be programmed, the value is pending until you program the device. On the screen, pending values appear in place of the permanent values initially displayed after an interrogation, and are shown with a dashed rectangular border.

CANCEL

A **CANCEL** button appears in the lower right portion of the value selection window. When you select this button, the window closes and the selected parameter value is not changed.

CLEAR PENDING

A **CLEAR PENDING** button appears in the value selection window when a pending value exists for the parameter whose value is being selected. When you select this button, the programmer clears the pending value for the selected parameter. To clear all pending values on one screen, select the **CLEAR PENDING** option from the **SPECIAL** menu.

Values Conflict

Present or pending values that conflict appear on the screen in shaded reverse or color video. These values must be changed to resolve the conflict.

Restricted Parameter s
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An italicized parameter value conflicts with another pending or present parameter value. The pending value and the value with which it conflicts appear as value conflicts on the parameter selection screen. You must select valid pending values that do not conflict.

Invalid Entry
???

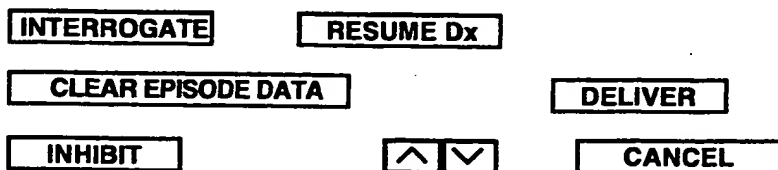
If programming fails because of telemetry interference, selected pending values remain on the screen, but present values are displayed with question marks. Reposition the programming head and repeat the programming.

Audible Signals

Single Mid-Tone Beep	The interrogation or programming was successful.
Double Mid- to Low-Tone Beep	The interrogation or programming was not successful.
Double Low-Tone Beep	Selected commands cannot be executed (e.g., cannot program because the programming head is out of position).
Single Short High-Tone Beep	Immediately after selecting PROGRAM or INTERROGATE , indicates that the programmer acknowledges the command.

On-Screen Buttons

Command buttons execute the programmer's operations (e.g., **INTERROGATE** the device, ☒ [decrease] a parameter's value, **DELIVER** a manual therapy, **SUSPEND Dx** [Detection]). Buttons ending in an ellipsis (...) open a window providing more specific selections. Buttons may have different sizes:

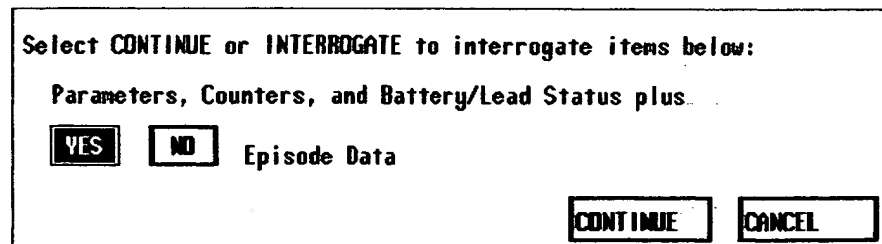


“Press and Hold” Buttons – To execute a “Press and Hold” temporary operation, position the touch pen over the button, then press the pen against the screen and continue to press for as long as you want the temporary function to operate. Lifting the pen cancels the temporary operation.

Interrogating the AMD

You may interrogate the AMD any time during a patient session except during Emergency functions. When you interrogate the AMD, the programmer first opens the window shown below, allowing you to specify the data to interrogate. If you choose not to interrogate the Episode Data, the interrogation time decreases.

All non-emergency programmer functions are unavailable during an interrogation.



Select CONTINUE or INTERROGATE to interrogate items below:
Parameters, Counters, and Battery/Lead Status plus
☐ YES ☐ NO Episode Data

Figure 12-4. Interrogation Dialog Window

◆ **How To Interrogate the AMD**

1. Position the programming head over the AMD.
2. Select **INTERROGATE**.
3. Select YES or NO for Episode Data.
4. Select **CONTINUE** or **INTERROGATE**.
5. If the interrogation fails, reposition the programming head and reselect **CONTINUE** or **INTERROGATE**.

Note: If an interrogation begins but fails to complete (because of telemetry interference, for example), you may select **CONTINUE** or **INTERROGATE** to resume interrogating from the point at which it stopped interrogating.

Unexpected Device Status Window – If the programmer displays an **Unexpected Device Status** window after the interrogation, a Device Status Indicator in the AMD has activated. Refer to “Device Status Indicators” on page 11-20.

Programmer Display Screen

Although the display screen changes as you perform different functions during a patient session, the screen format and screen features are similar throughout the application (Figure 12-5).

Menu Buttons – Menu buttons appear at the top of the display:

DATA **TESTS** **PARAMETERS** **END SESSION** **SPECIAL** **PRINT**

When you select a menu button, a menu (list of options) is displayed. You can then select a menu option using the touch pen. A checkmark (✓) indicates that the option is currently selected.

Message Line – Procedural prompts and status messages appear here when appropriate. It is important that you observe the message line while you are operating the programmer.

Value Selection Area – The central portion of the screen displays the parameters, value fields, and other on-screen buttons that apply to the selected function.

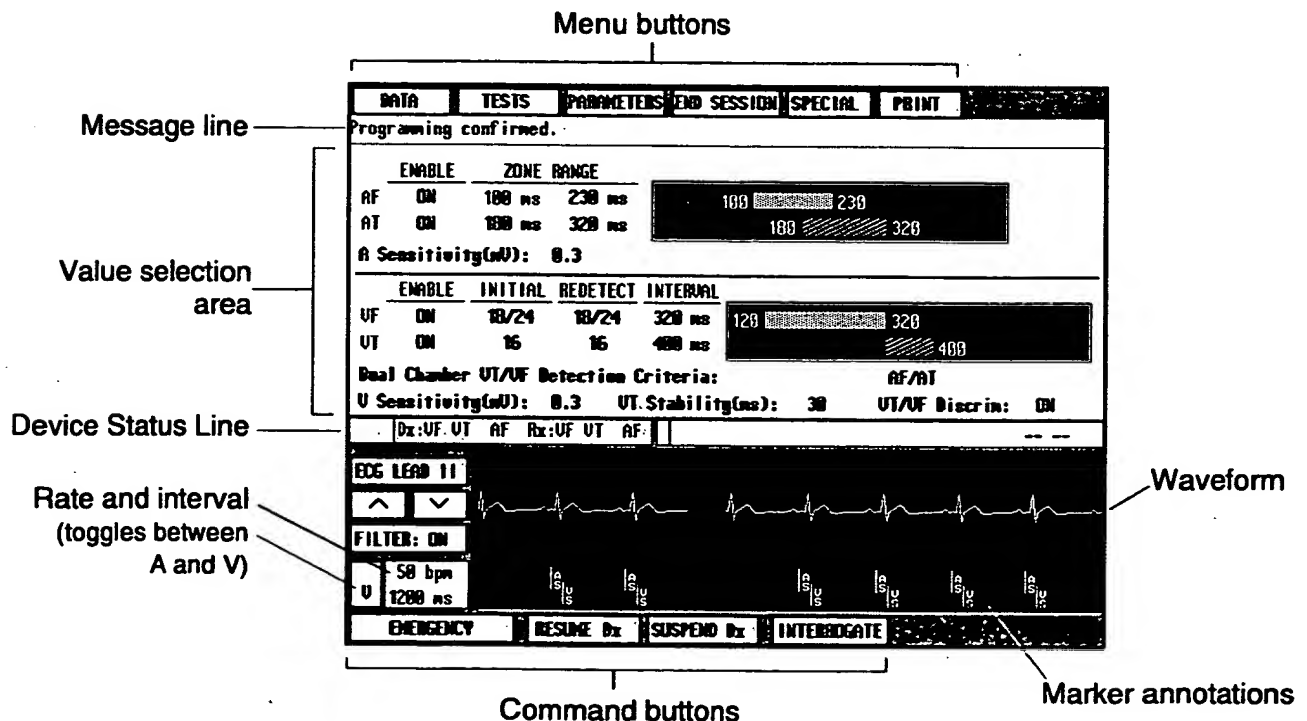


Figure 12-5. Typical Display Screen

Recording Real-Time Waveforms

Recording refers to real time recording of the ECG, EGM, and/or Marker Channel™ waveform traces and annotations. You can initiate a recording at any time during a patient session. If ECG electrodes are connected to the programmer, the recording includes the patient's ECG. If the programming head is properly positioned over the AMD, you can simultaneously record the EGM and Marker Channel™ waveforms telemetered from the AMD.

See page 11-13 for information on programming the EGM sources.

◆ **How To Start Recording**

- Press the desired paper speed key on the printer/recorder.

◆ **How To Stop Recording**

1. Press the paper speed key again.
2. Before tearing off the recording, press the **PAPER ADVANCE** key to advance the paper to a perforation.

◆ **Operating Considerations**

If you select an option from the **PRINT** menu, the programmer cancels the recording in progress.

The programmer cannot record the EGM trace until the current EGM Range setting has been interrogated from, or programmed to, the AMD.

If telemetry between the programmer and AMD is not successful, the programmer automatically retries an attempted transmission up to two times. This may result in multiple sets of programming and confirmation indicators being recorded.

You can program a new EGM Range setting during a recording. The programmer demarks the change with a vertical dotted line on the paper recording, and annotates it with the new gain setting.

The transmission of EGM and Marker Channel™ telemetry can be momentarily interrupted during an interrogation or programming or during capacitor charging.

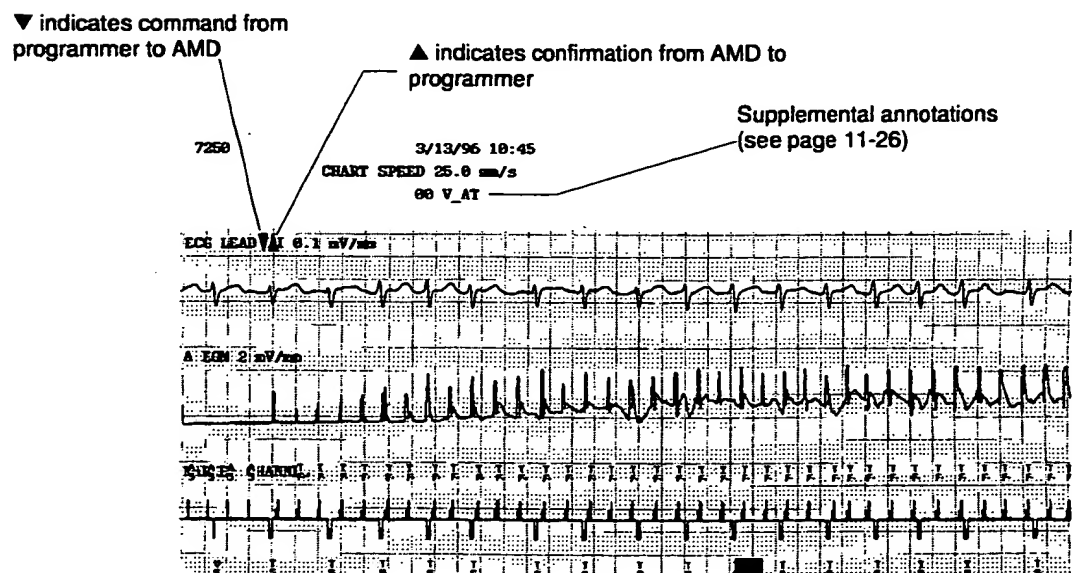


Figure 12-6. Real-Time Recording Example

Printing Reports

The programmer enables you to prepare printed records of the AMD system's operation, programming, and monitoring features:

- Printing reports of the device's status and settings.
- Printing stored records of detected tachyarrhythmia episodes, including stored EGMs.
- Real-time EGM, Marker Channel, and ECGs.

Printing refers to the generation of reports derived from the data and parameters retrieved from AMD memory. *Recording* refers to real time recording of the ECG, EGM, and/or Marker Channel™ waveform traces and annotations.

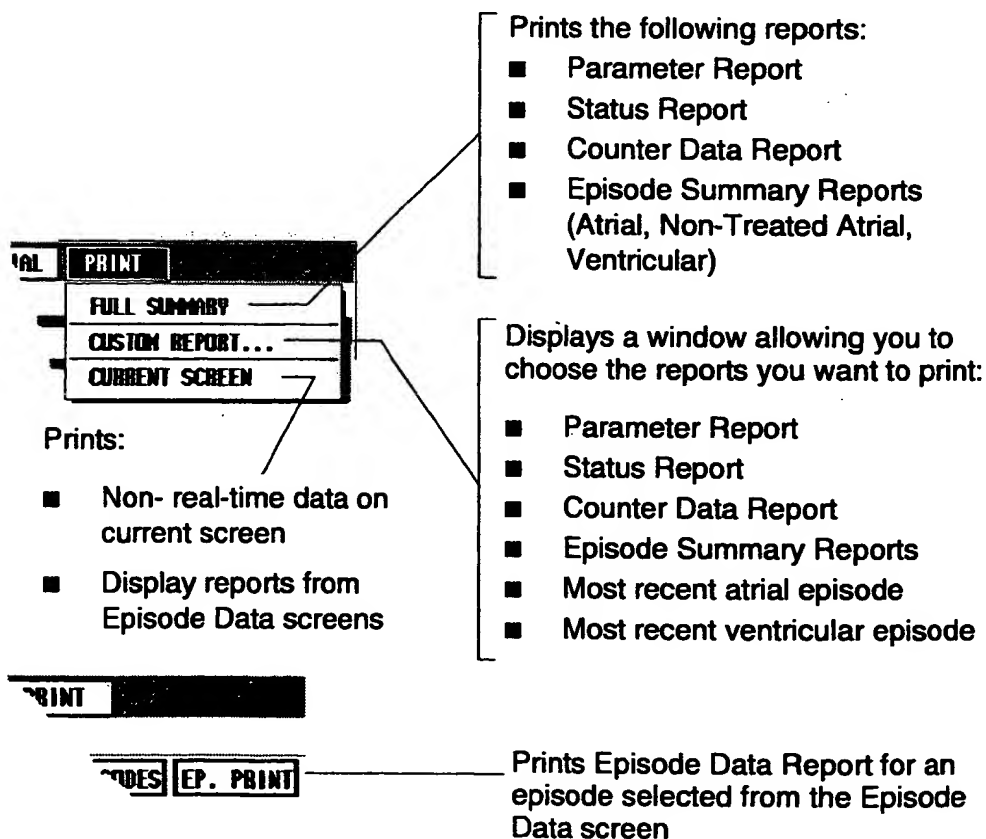


Figure 12-7. Printing Options

◆ **Operating Considerations**

Interrogate the AMD Before Printing – Before printing, you must interrogate the AMD for the specific type data you wish to print. If you try to print a report but have not interrogated the AMD for the data contained in the report, a message informs you that the data has not been interrogated.

How Printing Affects Other Programmer Functions – Selecting a report option causes the programmer to display a report generation message. While the message is displayed, data is being generated for printing. This may cause screen buttons except for **EMERGENCY** to be unresponsive. Emergency functions remain active throughout the report generation and printing process.

Printing a report cancels any in-process recording, but has no effect on other print selections, which remain queued to the printer/recorder. If you interrupt printing a report to execute an Emergency function, however, the programmer aborts the printing operation. It may also display the message

Printing reports cannot be completed due to an error on the disk.

In this context, the message indicates that the programmer appropriately deleted a temporary printing file, not that a disk failure occurred.

Running Out of Paper While Printing – If the printer/recorder runs out of paper while printing a report, load a new pad of paper into the printer (see the *9790c Programmer Description and Setup* manual provided with your programmer). Then reselect the same **PRINT** menu option. The programmer resumes printing from the point at which the paper ran out, but up to a page of the report will be lost.

◆ **How To Print a Full Summary Report**

- From the **PRINT** menu, select the **FULL SUMMARY** menu option. The programmer prints the Parameter (page 12-19), Status (page 12-20), Counter Data (page 11-5), and Episode Summary Reports (page 11-14).

◆ **How To Print a Custom Report**

1. From the **PRINT** menu, select the **CUSTOM REPORT...** menu option. The programmer displays a window that allows you to choose the report's contents (Figure 12-8).
2. Select **YES** or **NO** to specify the reports to be printed. The same Custom Report options remain selected throughout this patient session until you change them.
3. Select **PRINT CUSTOM REPORT**.

The screenshot shows a window titled "CUSTOM REPORT...". It contains several sections with "YES" and "NO" buttons for selection:

- PARAMETER SETTINGS: YES NO
- BATTERY/LEAD STATUS: YES NO
- COUNTER DATA: YES NO
- EPISODE SUMMARIES: YES NO
- LAST ATRIAL EPISODE: YES NO
- LAST VENTRICULAR EPISODE: YES NO

Below these sections, it says: "Printing of other episodes is available through the DATA menu."

At the bottom right, there are two buttons: "PRINT CUSTOM REPORT" and "CANCEL".

Figure 12-8. Custom Report Selection Window

◆ **How To Print a Current Screen Report**

- From the **PRINT** menu, select the **CURRENT SCREEN** menu option. The programmer prints the non-real-time portion of whatever textual or graphic data is currently visible on screen.

◆ **How To Print an Episode Data Report**

- From the **DATA** menu, select **EPISODE DATA**, highlight an atrial or ventricular episode, and select **EP. PRINT** (see page 11-16 for the contents of the report).

Parameter Report

The Parameter Report is a six-page printout of the programmed parameter values at the time of interrogation (Table 12-1).

Table 12-1. Parameter Report

Parameter	Page of Report
AF/AT Detection	1 of 6
VT/VF Detection	↓
Dual Chamber VT/VF Detection Criteria	↓
VT Stability (ms)	↓
VT/VF Discrimination	↓
VF Therapy (1 – 6)	2 of 6
VT Therapy (1 – 6)	↓
Duration of Sustained AF/AT Required to Initiate Therapy	3 of 6
A-Defib Daily Availability Window	↓
Time to Stop Therapy	↓
AF Therapies (1 – 6)	↓
AT Therapies (1 – 6)	↓
Patient Activated A-Defib Therapy	4 of 6
Shared Atrial Therapy Parameters	↓
Shared Ventricular Therapy Parameters	↓
Bradycardia Pacing Parameters	5 of 6
Mode Switch	↓
Ventricular Safety Pacing	↓
A-A Stabilization	↓
Holter Telemetry	6 of 6
Automatic Capacitor Formation Interval	↓
Most Recent Charge to Full Energy	↓
Last Capacitor Formation	↓
EGM Sources	↓

Status Report

The Status Report displays active Device Status Indicators and system status information (Table 12-2). Refer to "Battery/Lead Status" on page 11-17 for measurement information.

Table 12-2. Status Report

Category	Values
Device Status Indicators	CHARGE CIRCUIT = OK CHARGE CIRCUIT = TIME-OUT CHARGE CIRCUIT = INACTIVE
Battery Voltage	
Time of measurement	
Last measured voltage	
Most Recent Atrial Pacing Lead Impedance	
Time of measurement	
Impedance*	100 - 2000 Ω
Most Recent Ventricular Pacing Lead Impedance	
Time of measurement	
Impedance*	100 - 2000 Ω
Most Recent Charge	
Time of measurement	
Initial and final stored energy	
Charging time, in seconds	
Last Capacitor Formation	
Time of measurement	
Initial and final stored energy	
Stored energy after the charge	
Charging time, in seconds	
Most Recent High Voltage Lead Impedance	
Time of measurement	
Pathway(s)	
Delivered energy, in joules	
Impedance	20 to 200 Ω

* The impedance is averaged over the width of the pacing pulse, and may differ from measurements taken with other instruments such as the 5311 PSA.

Counter Data Report

The Counter Data Report (page 11-5) consists of the interrogated values of the episode and therapy counters.

Non-Treated Atrial Episode Summary Report

A Non-Treated Atrial Episode Summary Report (page 11-14) consists of an episode summary.

Atrial Episode Summary Report

An Atrial Episode Summary Report (page 11-14) consists of an episode summary.

Ventricular Episode Summary Report

A Ventricular Episode Summary Report (page 11-15) consists of an episode summary.

Episode Data Report

An Episode Data Report (page 11-16) consists of an episode summary, detection configuration, therapy sequences, therapy settings (atrial only), and EGM settings, followed by the EGM strip for the episode.

Saving AMD Data to a Disk

The programmer allows you to save up to 132K bytes of the most recently interrogated AMD data to a diskette inserted into the programmer's floppy disk drive. The data are saved in a special format intended for Medtronic use only.

◆ **How To Save AMD Data to a Floppy Diskette**

Note: Do not eject the diskette from the drive while a save is in progress. This can cause a disk error to occur.

1. From the menu, select **SAVE TO DISK**. If the AMD serial number has reset, the programmer prompts you to reprogram the serial number before saving.
2. Insert a diskette into the floppy disk drive.
3. Select to save data to the diskette or to cancel the operation.

◆ **Operating Considerations**

Emergency Functions During Save – During the save operation, the button remains displayed and all Emergency functions are available. If a disk error occurs during a save, however, there may be a delay in initiating the Emergency screens. Therefore, it is suggested that you not save to disk during EP studies or when a possibility exists that Emergency functions may be needed immediately.

Interrogate Before Saving – You need to interrogate the AMD before saving data to a diskette. The programmer displays an interrogation reminder: if you attempt to save but have not interrogated the AMD since starting the application; if you have programmed the AMD since the last interrogation; or if the last interrogation was unsuccessful.

Diskette Requirements – Use formatted, 3.5 inch, 720 KB (DS, DD) or 1.44 MB (DS, HD) diskettes. Be sure that you use an uncorrupted diskette. If you save data to a corrupted diskette, the programmer may become unresponsive. If this occurs, turn the programmer off and then on again. Normal operation should resume. Please inform your Medtronic representative of this occurrence.

Data File Names – Saved files are automatically named with a file name representing the date and time the file was saved. The naming convention is:

DDHHMMSS.PDD

DD	represents the day of the month (01 to 31)
HH	represents hours (24 hour clock)
MM	represents minutes
SS	represents seconds

“Disk Error” Messages – The programmer displays a **Save to Disk Error** message in the following instances:

Diskette is of the wrong type	Use a formatted, 3.5 inch 720 KB (DS, DD) or 1.44 MB (DS, HD) diskette.
Diskette is unformatted or improperly formatted	The diskette must be formatted with a version of MS-DOS or PC-DOS.
Diskette is write-protected	Check the write-protect switch on the back of the diskette.
Diskette is inserted improperly	The diskette must be inserted properly.
Diskette is faulty	If none of the above conditions apply, the diskette may be faulty. Try another diskette.

“Disk Full” message – The programmer displays a **Disk Full** message if there is not enough space available on the diskette. Make sure that the diskette has enough space for the data.

Reading AMD Data from a Disk

You may load AMD data previously saved to disk onto the programmer for viewing.

◆ **How To Read AMD Data from a Floppy Diskette**

Note: Do not eject the diskette from the drive while a read from disk is in progress. This can cause a disk error to occur.

1. From the menu, select **READ FROM DISK**.
2. Insert the data diskette into the floppy disk drive.
3. Select to read data from the diskette or to cancel the operation.

◆ **Operating Considerations**

The Read From Disk feature is not intended to be used when a patient is connected to the programmer.

Performing a Read From Disk operation disables the **Program** and **Interrogate** functions of the programmer. After reading data from a disk, you must end the session and then restart the 7250 application in order to program and/or interrogate a device.

Follow-Up

13

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AMD 13-6***

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Longevity Expectations

The longevity depends upon the programmed bradycardia pacing parameters, the percentage of paced to sensed events, the pacing load, and the frequency of high voltage capacitor charging. The longevity projections are based on the following conditions:

- 60 ppm pacing rate
- 4 V pacing pulse amplitude
- 0.4 ms pacing pulse width
- 510 Ω pacing load
- 48 lifetime charges to full energy (e.g., bi-monthly for eight years).

Table 13-1. Projected Longevity*

Pacing or Sensing	27 Joule Charging	Average Longevity
100% sensing	Every two months	8 years
100% VVI pacing	Every six weeks	5 years
100% DDD pacing	Monthly	4 years

* These preliminary longevity projections are based upon accelerated battery discharge data and device modeling. "Average" refers to the projected mean longevity of the modeled run of devices at the stated conditions.

The longevity decreases with:

- an increase in pacing rate.
- an increase in pacing amplitude or pulse width.
- a decrease in pacing impedance.
- an increase in the ratio of bradycardia paced to sensed events.
- an increase in the charging frequency.

Pacing amplitude may drop after the AMD reaches its replacement indicators. Consequently, the AMD may lose its bradycardia pacing capability before loss of tachyarrhythmia therapy capability.

Replacement Indicators

Table 13-2 below summarizes the voltage and charge time requirements at implant, Elective Replacement, and End of Life.

Elective Replacement Indicator (ERI)

Replacement of the AMD is recommended when the telemetered voltage for the battery is 4.94 V or less. This is an elective replacement indicator only, and does not indicate that the AMD has altered its operation in any way.

Note: Charge time is not required as a replacement indicator. Therefore, charging the capacitors at each follow-up session is unnecessary if Automatic Capacitor Formation is ON.

As the battery gradually depletes during the functional life of the device, the charge time will generally increase. Furthermore, the high voltage capacitors will require a longer charging time if they have not been charged for a longer period of time.

Table 13-2. Battery Voltage Indicators

Implant (Factory Settings)	≥ 6.10 V
Pacing mode and rate (magnet and non-magnet)	VVI, 60 ppm
Elective Replacement (ERI)	≤ 4.94 V
Pacing mode and rate (magnet and non-magnet)	as programmed
End of Life[*], † (EOL)	≤ 4.40 V
Pacing mode and rate (magnet and non-magnet)	as programmed

* If the charge time exceeds 30 seconds ("Charge Circuit Timeout" status message), the device is at EOL.

† When the device reaches EOL, the programmed parameters may initially be observed. However, as battery voltage further declines, the parameters will change to electrical reset values, and high voltage therapies can no longer be delivered.

End of Life (EOL) Indicators

Immediate replacement of the AMD is recommended under any of the following conditions:

- **When the telemetered voltage for the battery is 4.40 V or less.**

The AMD may be unable to successfully complete a charging cycle to the programmed energy. A charging period may terminate prematurely and result in the AMD assuming "Power-On Reset" parameter values (listed on page S-17 in the Specifications).

- **When a single charging period exceeds 30 seconds, regardless of capacitor formation status.**

If the output capacitors have not reached their full programmed charge in this time, the charge circuit "times out" (see page 11-20). After such a timeout, the AMD attempts to reconfirm episode detection and then resumes recharging.

Note: If after three consecutive 30-second charging periods the capacitors do not reach their programmed level, the AMD identifies a "Charge Circuit Inactive" state (see page 11-20). In this state, the AMD disables the following:

- automatic tachyarrhythmia therapies;
- all manual operations, except emergency VVI pacing.

End of Life means the AMD may be unable to successfully complete a charging cycle to the programmed energy.

Time Remaining After ERI

The time remaining after the Elective Replacement Indicator (ERI) is reached is four months (minimum)¹, based on the following:

- 100% DDD pacing at 60 ppm
- 4 V pulse amplitude
- 0.4 ms pulse width
- 510 Ω pacing load
- Four 27 J charging cycles

This time may be shorter with increased pacing rate, amplitude, or pulse width; lower pacing impedances; or an increase in high voltage capacitor charges.

1. The preliminary projection of the time remaining after ERI is based on accelerated battery data and AMD modeling. "Minimum" projection means that virtually all (99.9%) of the modeled production run of AMDs will attain the values given at the stated conditions.

Replacing An ICD with an AMD

◆ *How to Replace an ICD*

- 1.** Program VT, FVT and VF Detection OFF.
- 2.** Carefully dissect the leads and the AMD free from the surrounding tissues in the pocket. Be especially careful not to nick or breach the lead insulation inadvertently during the process of exposing the system.
- 3.** Insert the proper torque wrench through the slits in each rubber grommet and loosen the setscrew by turning counterclockwise.
- 4.** Gently retract each lead connector from its connector port. If any lead pin shows signs of pitting or corrosion, the entire lead should be evaluated and tested to assure the integrity of the system.
- 5.** Take pacing, sensing, and defibrillation efficacy measurements using an external implant support instrument.
- 6.** Insert new leads required for the AMD, if necessary.
- 7.** Connect the leads to the replacement AMD.
- 8.** Evaluate the defibrillation efficacy of the system.
- 9.** Implant the new AMD and close.
- 10.** Clear and interrogate the AMD, and print a full summary report to verify and document the programmed status of the AMD.
- 11.** Return the explanted ICD, after cleaning/gas sterilization, to your Medtronic representative for device evaluation.

Follow-up Visit Evaluation

After implantation, regular patient follow-up should be scheduled every six months to confirm that the programmed parameter values are appropriate and to monitor the condition of the implanted system and of the AMD's battery.

The physician should do the following during each follow-up visit:

- interrogate the AMD,
- review AMD experience and battery status,
- verify an adequate pacing threshold margin,
- evaluate pacing and sensing characteristics.

If a charge time-out occurs or if the initial battery voltage is 4.94 V or less, the AMD should be replaced.

The physician can acquire information about the present and past operation of the AMD via telemetry reports. These reports include:

- device status data,
- episode counter data,
- therapy counter data,
- episode data reports.

In the absence of Medtronic programming equipment, an ECG monitor/recorder system and a magnet can be used to stop A/V tachyarrhythmia detection.

Capacitor Formation

The AMD's capacitors must be formed (conditioned) periodically to maintain their ability to load and retain charge. The capacitors can be formed either automatically using the Automatic Capacitor Formation feature, or manually at each follow-up visit.

See page 13-9 for a more detailed description of Capacitor Formation.

◆ **Programmable Parameter (Automatic Cap Formation)**

AUTO CAP FORMATION INTERVAL	OFF or 1 – 6 months.
--	----------------------

◆ **Programming Considerations (Auto Cap Formation)**

When Automatic Capacitor Formation is OFF, a manual capacitor formation should be performed every six months.

Forming the capacitors more than every six months depletes the AMD's battery and decreases its longevity.

◆ **How to Program Automatic Capacitor Formation**

1. From the **PARAMETERS** menu, select **AUTO CAP FORMATION**.
2. Select an **AUTO CAP FORMATION INTERVAL** (months).

Automatic
Capacitor Formation
Interval
(circled)

DATA	TESTS	PARAMETERS	END SESSION	SPECIAL	PRINT
------	-------	------------	-------------	---------	-------

AUTO CAP FORMATION: Capacitor charges to maximum energy (27J).

SHOW PRESENT

AUTO CAP FORMATION INTERVAL (months): **6**

Note: changing value resets Formation Interval timer.

MOST RECENT CHARGE TO FULL ENERGY: No measurement since reset.	LAST CAPACITOR FORMATION: No measurement since reset.
--	---

◆ **How Capacitor Formation Works**

Capacitor formation consists of three steps: the capacitors are completely depleted; they charge to their full energy; and the charge is then allowed to dissipate for at least ten minutes.

To increase device longevity, the AMD resets or extends the automatic capacitor formation interval as follows:

- A manual capacitor formation resets the automatic capacitor formation interval clock.
- An incidental capacitor formation (e.g., an aborted therapy where a 27 J charge dissipates for 10 minutes) resets the automatic capacitor formation interval clock.
- Each 27 J charge that is delivered or dumped extends the automatic capacitor formation interval clock by up to two months. The total of these extensions will not exceed the programmed automatic capacitor formation interval.

◆ **How to Form the Capacitors Manually**

1. From the **TESTS** menu, select **TEST CHARGE**.
2. Toggle the **OPERATION TO PERFORM:** field to **DUMP**, then select **DELIVER**.

Test Charge/Dump
Operation to Perform
(circled)

DATA	TESTS	PARAMETERS	END SESSION	SPECIAL	PRINT
TEST CHARGE: Select DELIVER to charge capacitors to 27J.					
OPERATION TO PERFORM: CHARGE					
MOST RECENT CHARGE TO FULL ENERGY:			LAST CAPACITOR FORMATION:		
Oct 09, 1995 12:05:22			Oct 06, 1995 11:43:27		
Energy(J): 0.4 - 26.8			Time stamp updated when 27J		
Charge Time(sec): 5.23			charge held for 10 minutes.		

3. Toggle the **OPERATION TO PERFORM:** field to **CHARGE**, and select **DELIVER**.
4. After the charge completes successfully, select **INTERROGATE** or **CONTINUE** to verify that the charge began at 0.0 joules. Allow the charge to dissipate by itself for ten minutes.

Technical Support

Medtronic employs highly trained representatives and engineers located throughout the world to serve you and, upon request, to provide training to qualified hospital personnel in the use of Medtronic products.

In addition, Medtronic maintains a professional staff of consultants to provide technical consultation to product users. For medical consultation, Medtronic can often refer product users to outside medical consultants with appropriate expertise.

For more information, contact your local Medtronic representative, or call or write Medtronic at the appropriate address or telephone number listed on the back cover.

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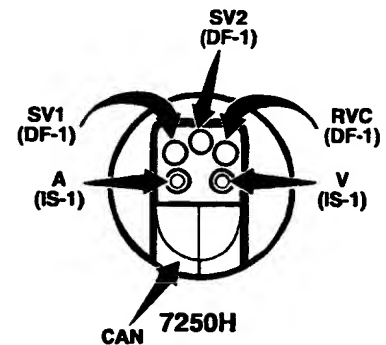
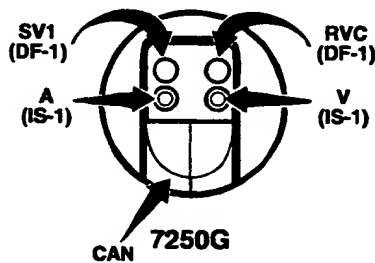
Physical Characteristics

	Model 7250G	Model 7250H
Volume	55 cc	56 cc
Mass	93 g	94 g
H x W x D	76 mm x 55 mm x 16 mm	79 mm x 55 mm x 16 mm
Surface area of device can	81.5 cm ²	81.5 cm ²
Radiopaque ID*	PIC	PID
Materials in contact with human tissue†	Titanium / polyurethane / silicone / rubber	
Battery	Lithium silver vanadium oxide (6.4 V nominal)	

* Engineering series number follows the radiopaque code.

† These materials have been successfully tested for the ability to avoid biological incompatibility. The device does NOT produce an injurious temperature in the surrounding tissue.

Lead Connections



Programmable Parameters¹

Table S-1. Detection Parameters (Sheet 1 of 2)

Parameter	Values	Tolerance	Notes
AF DETECTION PARAMETERS			
Detection Enable	ON, OFF		
Minimum AF Interval	100 ms (fixed)	± 2 ms	
AF Interval (ms)	150, 160, . . . , 300	± 2 ms	Note A.
A. Sensitivity (mV)	0.15, 0.3, 0.45, 0.6, 0.9, 1.2, 1.5, 2.1	± 75% ± 50% ± 30%	Note B, Note C.
AT DETECTION PARAMETERS			
Detection Enable	ON, OFF		
Minimum AT Interval (ms)	100, 110, . . . , 300	± 2 ms	Note A.
AT Interval (ms)	150, 160, . . . , 450	± 2 ms	Note A.
A. Sensitivity (mV)	0.15, 0.3, 0.45, 0.6, 0.9, 1.2, 1.5, 2.1	± 75% ± 50% ± 30%	Note B, Note C.
VF DETECTION PARAMETERS			
Detection Enable	ON, OFF		
Initial NID	12/16, 18/ 24, 24/32		
Redetect NID	6/8, 9/12, 12/16, 15/20, 18/24, 21/28, 24/32		
V. Sensitivity (mV)	0.15, 0.3, 0.45, 0.6, 0.9, 1.2	± 75% ± 50% ± 30%	Note B, Note C.
Interval (ms)	240, 250, . . . , 400	± 2 ms	Note A.

1. Using Model 9958E application software. Programming configurations may change due to Medtronic's continuing development.

Specifications
Programmable Parameters

Table S-1. Detection Parameters (Sheet 2 of 2)

Parameter	Values	Tolerance	Notes
VT DETECTION PARAMETERS			
Detection Enable	ON, OFF		
Initial NID	12, 16, . . . , 28		
Redetect NID	8, 12, . . . , 28		
V. Sensitivity (mV)	0.15, 0.3, 0.45, 0.6, 0.9, 1.2	± 75% ± 50% ± 30%	Note B, Note C.
Interval (ms)	280, 290, . . . , 600	± 2 ms	Note A, Note D.
VT Stability Criterion Parameters			
VT Stability (ms)	OFF, 30, 40, . . . , 100	± 2 ms	Note A.
VT/VF Discrimination Parameters			
VT/VF Discrim	ON, OFF		
DUAL CHAMBER VT/VF DETECTION			Note E.
AF/AT	ON, OFF		
Sinus Tach	ON, OFF		
Other 1:1 SVTs	ON, OFF		
SVT Minimum Interval (ms)	240, 250, . . . , 600	± 2 ms	

Table S-2. Ventricular Therapy Parameters (Sheet 1 of 3)

Parameter	Values	Tolerance	Notes
VF THERAPY PARAMETERS			Note G.
Therapy Status	ON, OFF		
Energy (J)	0.2, 0.4, . . . , 1.8, 2, 3, . . . , 16, 18, 20, 22, 24, 27	± 10%	Note H.
Pathway	(Any combination)		Note I.

Table S-2. Ventricular Therapy Parameters (Sheet 2 of 3)

Parameter	Values	Tolerance	Notes
VT THERAPY PARAMETERS			
V-Cardioversion Therapy Parameters			Note G.
Therapy Status	ON, OFF		
Energy (J)	0.2, 0.4, . . . , 1.8, 2, 3, . . . , 16, 18, 20, 22, 24, 27	± 10%	
Pathway	(Any combination)		Note I.
CV Delay (ms)	0, 20, . . . , 300	± 50 ms	Manual Rx only.
V-Burst Pacing Therapy Parameters			Note G.
Therapy Status	ON, OFF		
Initial # Pulses	1, 2, . . . , 15		
R-S1 Interval (% of R-R)	50, 53, 56, 59, 63, 66, . . . , 84, 88, 91, 94, 97	± 1%	
# Sequences	1, 2, . . . , 10		
Pacing Interval Decrement (ms)	0, 10, . . . , 40	± 1 ms	

Specifications
Programmable Parameters

Table S-2. Ventricular Therapy Parameters (Sheet 3 of 3)

Parameter	Values	Tolerance	Notes
V-Ramp Pacing Therapy Parameters			Note G.
Therapy Status	ON, OFF		
Initial # Pulses	1, 2, . . . , 15		
R-S1 Interval (% of R-R)	50, 53, 56, 59, 63, 66, . . . , 84, 88, 91, 94, 97	± 1%	
# Sequences	1, 2, . . . , 10		
Pacing Interval Decrement, within a Sequence (ms)	0, 10, . . . , 40		
V-Ramp-Plus Pacing Therapy Parameters			Note G.
Therapy Status	ON, OFF		
Initial # Pulses	1, 2, . . . , 15		
R-S1 Interval (% of R-R)	50, 53, 56, 59, 63, 66, . . . , 84, 88, 91, 94, 97	± 1%	
S1-S2 Interval (% of R-R)	50, 53, 56, 59, 63, 66, . . . , 84, 88, 91, 94, 97	± 1%	
S2-Sn Interval (% of R-R)	50, 53, 56, 59, 63, 66, . . . , 84, 88, 91, 94, 97	± 1%	
# Sequences	1, 2, . . . , 10		
SHARED PARAMETERS FOR VENTRICULAR THERAPIES			
Shared by all Automatic V-Defib and V-Cardioversion Therapies			
Tilt (%)	50, 65	± 5%	30,40,50,65 for manual therapy
Shared by all Automatic V-ATP Therapies			Note G.
Pulse Width (ms)	0.03, 0.06, 0.1, 0.2, . . . , 1.5	-0, +0.03 ms ± 0.05 ms	
Amplitude (V)	1, 2, . . . , 6, 8	± 30%	
Pace Blank (ms)	200, 210, . . . , 440	-30, +5 ms	
V-ATP Minimum Interval (ms)	150, 160, . . . , 400	± 2 ms	

Table S-3. Atrial Therapy Parameters (Sheet 1 of 3)

Parameter	Values	Tolerance	Notes
AUTOMATIC AF/AT THERAPY SEQUENCING			
Duration of Sustained AF/AT Required to Initiate Automatic Therapy			
Pacing Therapies	0, 1, . . . , 5 minutes, 7, 10, 15, 20 minutes, 25, 30, 40, 50 min, 1, 2, . . . , 6 hours, 12 hours, 24 hours	± 2%	
A-Defib Therapies	0, 1, . . . , 5 minutes, 7, 10, 15, 20 minutes, 25, 30, 40, 50 min, 1, 2, . . . , 6 hours, 12 hours, 24 hours	± 2%	
Automatic A-Defib Daily Availability Window Parameters			
Maximum A-Defibs (per window)	1, 2, . . . , 8, UNLIMITED		
A-Defib Window Start	00:00, 1:00, . . . , 23:00	± 1 hour per year	
A-Defib Window Length (hours)	1, 2, 3, 4, 6, 8, 10, 12, 16, 20, 24	± 20%	
Time to Stop Therapy Parameters			
Time to Stop Therapy (hours)	NONE, 12, 24, . . . , 72	± 2%	
AUTOMATIC AF/AT THERAPY PARAMETERS			
Atrial Defibrillation Therapy Parameters			
Energy (J)	0.1, 0.2, 0.4, . . . , 1.8, 2, 3, . . . , 16, 18, 20, 22, 24, 27	± 10%	Note G. Note J.
Pathway	(Any combination)		Note I.
Synchronization	V-ONLY, A +V		
A-50 Hz (High Freq.) Burst Pacing Therapy Parameters			
Burst Duration (seconds)	1, 2, 3	± 2%	Note G.
# Sequences	1, 2, . . . , 9, 10, 15, . . . , 30, 40, 50, . . . , 100		

Specifications
Programmable Parameters

Table S-3. Atrial Therapy Parameters (Sheet 2 of 3)

Parameter	Values	Tolerance	Notes
A-Ramp Pacing Therapy Parameters			Note G.
Initial # Pulses	1, 2, . . . , 15, 20, 30, . . . , 100		
A-S1 Interval = (%AA)	28, 31, 34 38, 41, . . . , 59 63, 66, . . . , 84 88, 91, 94, 97	± 1%	
Interval Decrement (ms)	0, 10, . . . , 40	± 1 ms	
# Sequences	1, 2, . . . , 10		
A-Burst-Plus Pacing Therapy Parameters			Note G.
Initial # Pulses	1, 2, . . . , 15, 20, 30, . . . , 100		
A-S1 Interval = (%AA)	28, 31, 34 38, 41, . . . , 59 63, 66, . . . , 84 88, 91, 94, 97	± 1%	
S1-S2 Interval = (%AA)	OFF, 28, 31, 34 38, 41, . . . , 59 63, 66, . . . , 84 88, 91, 94, 97	± 1%	
S2-S3 Interval = (%AA)	OFF, 28, 31, 34 38, 41, . . . , 59 63, 66, . . . , 84 88, 91, 94, 97	± 1%	
# Sequences	1, 2, . . . , 10		
PATIENT ACTIVATED A-DEFIB THERAPY			
Therapy Status	ON, OFF		
Energy (J)	0.1, 0.2, 0.4, . . . , 1.8, 2, 3, . . . , 16, 18, 20, 22, 24, 27	± 10%	Note J.
Pathway	(Any combination)		Note I.
Synchronization	V-ONLY, A + V		

Table S-3. Atrial Therapy Parameters (Sheet 3 of 3)

Parameter	Values	Tolerance	Notes
SHARED PARAMETERS FOR ATRIAL THERAPIES			
Shared by all Automatic and Patient-Activated A-Defib Therapies			Note G.
Tilt (%)	30, 40, 50, 65	± 5%	Same for manual therapy.
A-Defib Vent. Refractory (ms)	350, 360, . . . , 600	± 2 ms	
Shared by all Automatic A-ATP Therapies			Note G.
Pulse Width (ms)	0.03, 0.06, 0.1, 0.2, . . . , 1.5	-0, +0.03 ms ± 0.05 ms	
Amplitude (V)	1, 2, . . . , 6, 8	± 30%	
Pace Blank (ms)	200, 210, . . . , 440	- 30, + 5 ms	
Minimum A-A Interval (ms)	100, 110, . . . , 400	± 2 ms	

Specifications
Programmable Parameters

Table S-4. Bradycardia Pacing Parameters (Sheet 1 of 2)

Parameter	Values	Tolerance	Notes
Pacing Mode	DDD, DDI, AAI, VVI, OFF		
Lower Rate (ppm)	34, 36, . . . , 90, 95, 100, . . . , 120	± 2 ppm	Note D.
Upper Rate (ppm)	80, 82, . . . , 90, 95, 100, . . . , 120	± 2 ppm	Note D.
A.Sensitivity (mV)	0.15, 0.3, 0.45, 0.6, 0.9, 1.2, 1.5, 2.1	$\pm 75\%$ $\pm 50\%$ $\pm 30\%$	Note B, Note C.
A.Pulse Width (ms)	0.03, 0.06, 0.1, 0.2, . . . , 1.5	-0, +0.03 ms ± 0.05 ms	
A.Pulse Amplitude (V)	1, 2, . . . , 6	$\pm 30\%$	
A.Pace Blanking (ms)	200, 210, . . . , 440	- 30, + 5 ms	
V. Sensitivity (mV)	0.15, 0.3, 0.45, 0.6, 0.9, 1.2	$\pm 75\%$ $\pm 50\%$ $\pm 30\%$	Note B, Note C.
V.Pulse Width (ms)	0.03, 0.06, 0.1, 0.2, . . . , 1.5	-0, +0.03 ms ± 0.05 ms	
V.Pulse Amplitude (V):	1, 2, . . . , 6	$\pm 30\%$	
V.Pace Blanking (ms):	200, 210, . . . , 440	- 30, + 5 ms	
Intervals			
PAV (ms)	30, 40, . . . , 250	± 2 ms	
SAV (ms)	30, 40, . . . , 250	- 2, + 32 ms	
PVARP (ms)	150, 160, . . . , 500	- 32, + 2 ms	
ARP (ms)	150, 160, . . . , 500	- 32, + 2 ms	

Table S-4. Bradycardia Pacing Parameters (Sheet 2 of 2)

Parameter	Values	Tolerance	Notes
Mode Switch Parameters			
Enable	ON, OFF		
DDI Rate (ppm)	34, 36, . . . , 90, 95, 100, . . . , 120	± 2 ppm	
Switchback Delay	NONE, 30 seconds, 1, 2, 3, 5, 10, 20 minutes, 30 min., 1 hour, 2 hours	$\pm 10\%$	
Ventricular Safety Pacing Parameters			
Ventricular Safety Pacing	ON, OFF		
Atrial Rate Stabilization Parameters			
Atrial Rate Stabilization	ON, OFF		
Increment (ms)	100, 150, . . . , 400	± 2 ms	

Table S-5. EP Studies Parameters

Parameter	Values	Tolerance	Notes
INDUCTIONS			
A/V PES Induction Parameters			
#S1	1, 2, . . . , 15, 20, 30, . . . , 100		
S1S1 (ms)	100, 110, . . . , 1760	- 2, + 32 ms	Mode VVI.
S1S2 (ms)	OFF, 100, 110, . . . , 600	± 2 ms	Mode VOO.
S2S3 (ms)	OFF, 100, 110, . . . , 600	± 2 ms	Mode VOO.
S3S4 (ms)	OFF, 100, 110, . . . , 600	± 2 ms	Mode VOO.
Pulse Amplitude (V)	1, 2, . . . , 6, 8	± 30%	
Pulse Width (ms)	0.03, 0.06, 0.1, 0.2, . . . , 1.5	-0, +0.03 ms ± 0.05 ms	
A/V 50 Hz Burst Induction Parameters			
Interval (ms)	20 ms (fixed)	± 2 ms	
Pulse Amplitude (V)	1, 2, . . . , 6, 8	± 30%	
Pulse Width (ms)	0.03, 0.06, 0.1, 0.2, . . . , 1.5	-0, +0.03 ms ± 0.05 ms	
V T-Shock™ Induction Parameters			
#S1	2 – 8		
S1S1 (ms)	350, 360, . . . , 1760	± 2 ms	
Delay (ms)	50, 60, . . . , 600	± 2 ms	
Energy (J)	0.2, 0.4, . . . , 1.8, 2, 3, . . . , 16, 18, 20, 22, 24, 27	± 10%	
Pathway	(Any combination)		Note I.
Waveform	MONO or BIPH		
Pulse Amplitude	6 V (fixed)	± 30%	
Pulse Width	1.5 ms (fixed)	± 0.05 ms	
Enable	ON, OFF		
Manual Therapy Parameters			
In general, manual therapy uses the same parameter values as the automatic therapy. See "Ventricular Therapy Parameters" beginning on page S-4, and "Atrial Therapy Parameters" beginning on page S-7.			

Table S-6. Recording Mode Parameters

Parameter	Values	Tolerance	Notes
Holter Telemetry Parameters			
Duration (hours)	OFF, 0.5, 1, 2, 4, 8, 16, 24, 36, 46	± 5%	

Table S-7. Automatic Capacitor Formation Parameters

Parameter	Values	Tolerance	Notes
Automatic Capacitor Formation Interval (months):	OFF, 1, 2, . . . , 6	± 0.125 months	

Table S-8. EGM Source Parameters

Parameter	Values	Tolerance	Notes
EGM Source (Channel 1 / Channel 2)	Wideband / A-Sense Wideband / V-Sense A-Sense / V-Sense V-Sense / A-Sense		Note K.
Wideband Source	A-Tip to V-Ring A-Tip to A-Ring A-Ring to V-Ring V-Tip to V-Ring		
Wideband Range (mV)	± 4, ± 8, ± 16, ± 32	- 0, + 10%	

Fixed Parameters

Table S-9. Fixed Parameters (Sheet 1 of 2)

Parameter	Value (Tolerance)	Notes
SENSING		
Atrial Blanking Periods		
After a sensed atrial event	100 ms (- 30, + 0 ms)	
After a paced vent. event	30 ms (\pm 2 ms)	
After charging ends	300 ms (- 40, + 100 ms)	
After HV therapy	520 ms (\pm 30 ms)	
Ventricular Blanking Periods		
After a sensed vent. event	120 ms (- 30, + 0 ms)	
After a paced atrial event	30 ms (\pm 2 ms)	
After charging ends	300 ms (- 40, + 100 ms)	
After HV therapy	520 ms (\pm 30 ms)	
Atrial Refractory Periods		
Atrial Defibrillation ARP	A-Defib. VRP plus 50 ms (\pm 2 ms)	
Ventricular Refractory Periods		
After sense during CV synch.	200 ms (\pm 30 ms)	
After charge during DF synch.	400 ms (- 40, + 100 ms)	
BRADYCARDIA PACING		
PVC Response (PVARP extension)	Extended to 400 ms	Note L.

Table S-9. Fixed Parameters (Sheet 2 of 2)

Parameter	Value (Tolerance)	Notes
HIGH VOLTAGE THERAPIES		
Maximum charging period	30 seconds (- 0, + 2 s)	
Waveform	Biphasic	
Separation of phases	244 μ s (- 225, + 500 μ s)	
Reconfirm VF after Charge	YES	First automatic VF Rx only.
VF Synchronization Periods		Note M.
After post-charge blanking	500 ms (\pm 2 ms)	
After a sensed event	500 ms (- 0, + 30 ms)	
Patient-Activated Therapies		
Therapy Type	A-Defibrillation	
POST-THERAPY		
Escape interval after CV/Defib	1200 ms (\pm 2 ms)	1760 ms if pacing is OFF.
Pacing output after CV/Defib	1.5 ms (\pm 0.05 ms) at 6 V (\pm 2 V)	
Suspension of AF and AT detection after A-50 Hz Burst pacing therapy	16 ventricular events	
Suspension of AF therapies after A-Ramp or A-Burst+ Rx	4 minutes	
Suspension of VT Detection after V-Defib therapy	17 ventricular events	
EP STUDIES		
T-Shock™ S1 pacing outputs	1.5 ms (\pm 0.05 ms) at 6 V (\pm 2 V)	Mode VVI.
Atrial rate limit (protective feature)	180 ppm (\pm 2 ppm)	Note N.
Ventricular rate limit (protective feature)	180 ppm (\pm 2 ppm)	Note N.
Input protection	50 k Ω minimum	

Emergency Settings

Table S-10. Emergency Settings

Parameter	Emergency Value
DEFIBRILLATION	
Energy	10, 11, . . . , 16 J 18, 20, 22, 24, 27 J (27 J default)
Pathway	CAN → RVC
CARDIOVERSION	
Energy	0.2, 0.4, . . . , 1.8 J, 2, 3, . . . , 16 J 18, 20, 22, 24, 27 J (27 J default)
Pathway	CAN → RVC
VVI PACING	
Pacing Mode	VVI
Pacing Rate	70 ppm
Pulse Amplitude	6 V
Pulse Width	1.5 ms
V. Sensitivity	As programmed
Pace Blanking	As programmed

Power-On Reset Settings

Table S-11. Power-On Reset Settings

Parameter	Reset Value
Pacing Mode	VVI
Pacing Rate	60 ppm
V. Pulse Width	0.5 ms
V. Amplitude	5 V
V. Sensitivity	0.3 mV
Pace Blanking	250 ms
AF / AT Detection & Therapies	OFF
VT Detection & Therapies	OFF
Dual Chamber VT/VF Detection:	
AF/AT	OFF
Sinus Tachycardia	OFF
Other 1:1 SVTs	OFF
VF Detection	ON
VFDI	320 ms
Initial NID	18/24
Redetect NID	18/24
VF Therapies 1 - 6	ON
Energy	27 joules
Pathway	CAN → RVC
EGM Channel 1 (episode record)	A _{Tip} to V _{Ring}
Auto. Cap. Formation Interval	6 months

Factory Shipped Settings

Table S-12. Factory Shipped Settings

Parameter	Factory Shipped Setting
Pacing Mode	VVI
Pacing Rate	60 ppm
V. Pulse Width	0.4 ms
V. Amplitude	4 V
V. Sensitivity	0.3 mV
Pace Blanking	250 ms
AF / AT Detection & Therapies	OFF
VT Detection & Therapies	OFF
Dual Chamber VT/VF Detection	
AF/AT	ON
Sinus Tachycardia	ON
Other 1:1 SVTs	ON
VF Detection	OFF
VFDI	320 ms
Initial NID	18/24
Redetect NID	18/24
VF Therapies 1 - 6	ON
Energy	27 joules
Pathway	CAN>RVC
EGM Channel 1 (episode record)	A _{Tip} to V _{Ring}
Automatic Cap. Formation Interval	OFF

Measurements

Table S-13. Circuit and Device Measurements

Category	Tolerance
Battery voltage	$\pm 10\%$
Stored energy	$\pm 20\%$ or 0.1 J, whichever is greater.
Charging time	± 100 ms
Delivered energy	$\pm 25\%$ or 0.1 J, whichever is greater.
Pacing Lead Impedance	$\pm 20\%$ (at implant)
High Voltage Pathway Impedance*	(+ 50, - 30 %)

* Using a monophasic 0.2 J pulse.

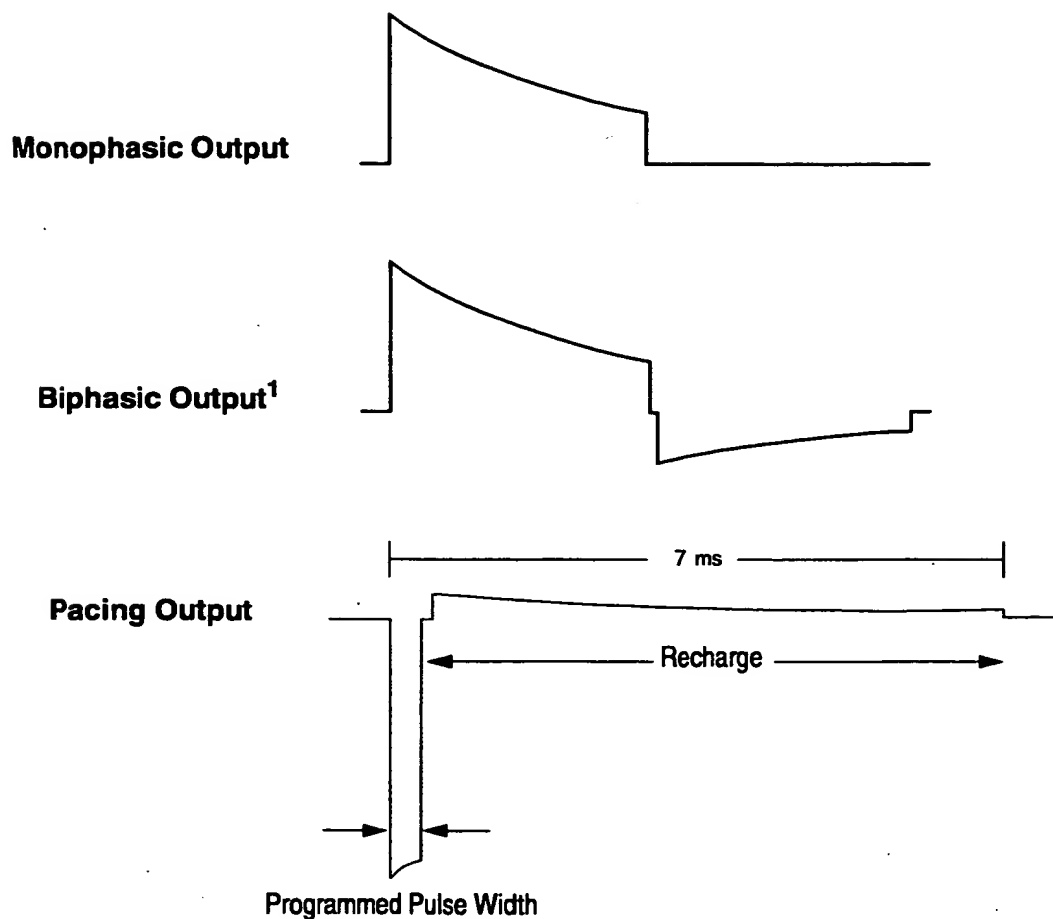
Magnet Application

Table S-14. Magnet Application

Pacing Mode	as programmed
Pacing Rate and Interval	as programmed
AF/AT Detection	suspended
VF/VT Detection	suspended

Output Waveforms

Output Waveforms



1. Very low energy biphasic shocks (0.2 J or less) may terminate prematurely after the first phase, due to the relatively low voltages employed.

Notes

- Note A: The measured intervals are truncated to a 10 ms multiple (e.g., 457 ms becomes 450 ms). The device uses this truncated interval value when applying the programmed criteria and calculating interval averages.
- Note B: With a 40 ms sine² waveform. When using the Cenelec waveform, the rated sensing threshold value will be 1.5 times the rated sine² sensing threshold.
- Note C: This setting applies to all tachyarrhythmia detection and bradycardia pacing in this chamber.
- Note D: The (upper rate) pacing escape interval must exceed any programmed ventricular Detection Interval by at least 60 ms. In dual chamber modes, the longest V-A interval (lower rate escape minus PAV) must equal or exceed any programmed ventricular Detection Interval.
- Note E: Dual tachyarrhythmia ("VF+SVT" and "VT+SVT") detection is automatically enabled when any Dual Chamber VT/VF Detection criterion is enabled.
- Note F: Nominal value is blank until detection is enabled.
- Note G: These specifications apply to both automatic and manual therapies, except as noted.
- Note H: For automatic therapy 3, 4, 5, or 6, energy must be at least 10 joules.
- Note I: If RVC is used, then CAN must oppose it.
- Note J: The second phase of a 0.1 J pulse may be truncated if the tilt is greater than 50%.
- Note K: The "Channel 1" EGM is stored in Episode Records; both channels appear on-screen as real-time telemetered signals.
- Note L: If [LRI minus PAV minus 300 ms] is less than 400 ms, then PVARP is extended to that value. If the programmed PVARP exceeds the PVC Response PVARP, the programmed value is used.
- Note M: On the first VF therapy attempt, the shock is not committed (page 8-11).
- Note N: Does not apply during therapies or programmed high rates.
- Note O: The time displayed is dependent on the device's date/time clock.

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